IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**No. 1:19-md-2875-RBK**

EXPERT DECLARATION OF RENA CONTI, PH.D.

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I. EXECUTIVE SUMMARY

1. I have been retained by Plaintiffs' Counsel to provide opinions and calculations regarding the injury and damages incurred by Classes of consumers and end-payors in this matter.[1] To do so, I must assign an economic value to prescription drugs that were adulterated and misbranded.

2. I have been asked by Plaintiffs' Counsel to assume that the at-issue Valsartan products manufactured and sold by defendants Zheijiang Huahai Pharmaceutical Co., Ltd ("ZHP"), Hetero Labs, Ltd. ("Hetero"), Mylan Laboratories, Ltd. ("Mylan"), Aurobindo Pharma, Ltd. ("Aurobindo"), Teva Pharmaceutical Industries, Ltd. ("Teva"), and Torrent Pharmaceuticals, Ltd. ("Torrent") (collectively referred to as "the Defendant Manufacturers")[2] into the United States pharmaceutical chain, from January 1, 2012 until the at-issue Valsartan products were recalled in 2018 and 2019,[3] were adulterated and misbranded.[4]

3. Plaintiffs' Counsel have also asked me to assume that a subset of these at-issue Valsartan products were sold by defendants AmerisourceBergen Co., Cardinal Health, and McKesson Co.

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[1] Third Amended Consolidated Economic Loss Class Action Complaint, *In re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, United States District Court for the District of New Jersey, No. 1:19-md-2875-RBK, Docket Entry No. 1708 (hereafter, "Complaint").

[2] Complaint, Sections II.C and II.D.

[3] See FDA, "FDA Updates and Press Announcements on Angiotensin II Receptor Blockers (ARB) Recalls (Valsartan, Losartan, and Irbesartan), available at https://www fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan, which shows the following months for final recalls for each of the Defendant Manufacturers:

- July 2018 for ZHP;
- July 2018 for Teva's generic Diovan products (Valsartan and Valsartan Hydrochlorothiazide (HCTZ));
- August 2018 for Hetero (when its subsidiary, Camber Pharmaceuticals, was added to the recall list);
- August 2018 for Torrent;
- November 2018 for Teva's generic Exforge products (Amlodipine Valsartan and Amlodipine Valsartan HCTZ);
- December 2018 for Mylan;
- March 2019 for Aurobindo.

[4] According to the Complaint, these at-issue Valsartan products were contaminated with N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA), both of which which rendered them adulterated and misbranded. See Complaint, Section IV.N.

(collectively referred to as "the Defendant Wholesalers")[5] and that a subset of these at-issue Valsartan products were sold by defendants Albertsons, CVS, Express Scripts, Kroger, Optum Rx, Rite-Aid, Walgreens, and Walmart (collectively referred to as "the Defendant Retailers").[6]

4. The adulteration derives from the Defendant Manufacturers' allowance of chronic and pervasive deficiencies in the manufacturing of at-issue Valsartan products, and the Defendant Manufacturers' failure to implement quality assurance practices that would have uncovered the problems prior to these products entering the United States pharmaceutical supply chain. The manufacturing and production practices for these at-issue Valsartan products by the Defendant Manufacturers were materially non-compliant with current Good Manufacturing Practices ("cGMPs) and utilized chemical practices and materials that resulted in the creation of known carcinogens as a byproduct. The at-issue Valsartan products manufactured and sold by the Defendant Manufacturers were not produced in a manner that matched the United States Food and Drug Administration's ("FDA") approved label, nor did they contain ingredients matching the product's FDA-approved label; consequently, they were misbranded. Specifically, the at-issue Valsartan products sold by the Defendants and purchased by consumers and end-payors lacked the assurance that they had the safety, identity, strength, quality, or purity that they were represented to possess to consumers and other payers, contrary to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 351.

5. I have also been asked by Plaintiffs' Counsel to assume that the Defendants are liable for the sale of adulterated and misbranded at-issue Valsartan products in the United States pharmaceutical supply chain during the period of January 1, 2012 until the at-issue Valsartan products were recalled in 2018.[7] The Defendants did so without informing consumers, payers, or the public at large of the non-compliant manufacturing practices of the at-issue Valsartan

[5] Complaint, Section II.F.

[6] Complaint, Section II.E. Collectively, I refer to the combined set of defendants (Manufacturers, Wholesalers, and Retailers) as "the Defendants" or "Defendant."

[7] The drugs manufactured by the defendants include all products containing Valsartan, including Valsartan, Valsartan Hydrochlorothiazide (HCT) (generics of brand drug Diovan); Amlodipine-Valsartan and Amlodipine-Valsartan HCT (generics of the brand drug Exforge) (hereafter, the "at-issue Valsartan products" or the "non-compliant drugs").

products, or of the fact that these products were adulterated, contained active ingredients that were not listed on the FDA-approved labelling, and, consequently, were misbranded.

6. Federal law, as codified by regulations of the FDA under the FDCA, mandates that prescription drugs be produced in accordance with cGMPs to assure that the drugs meet legal requirements for safety, and that they have the quality, purity, identity, and strength that they are represented to possess. Prescription drugs that are adulterated and misbranded are neither recognized by the United States government as legitimate products to be sold by manufacturers nor paid for by payers; nor are they considered legitimate products by the pharmaceutical industry. This non-product status is the result of longstanding efforts by the government, pharmaceutical companies and other parties participating in the United States pharmaceutical supply chain to protect the American public from the consumption of potentially harmful substances.

7. In the United States, when consumers purchase and third-party payers pay for an FDA-approved prescription drug, they are purchasing a product produced in accordance with cGMPs and with the manufacturer's assurance that the drugs meet legal requirements for safety, and that they have the quality, purity, identity, and strength that they are represented to possess on the FDA-approved label. Such products are assigned a non-zero economic value by consumers and third-party payers. Conversely, prescription drugs that are adulterated and misbranded have no economic value, they are worthless.

8. Consequently, the appropriate measure of damages in this matter is the total amount paid by each plaintiff for the at-issue Valsartan products manufactured and/or sold by the Defendants.

9. Using well-accepted economic methods and available data (purchased IQVIA data and retail pharmacy data produced through discovery), I can calculate aggregate economic damages resulting from the Defendants sale of the at-issue Valsartan products which were chronically and pervasively non-cGMP compliant, adulterated and misbranded. I have done so in aggregate and for each plaintiff class (End-Payor Class and Consumer Class). I have calculated that aggregate damages against the Defendant Manufacturers amount to [redacted] for the End-Payor Class and [redacted] for the Consumer Class, for a total of [redacted]. I have calculated that aggregate damages against the Defendant Retailers amount to [redacted] for the Consumer

Class. I have calculated that aggregate unjust enrichment damages against the Defendant Retailers amount to [redacted] for the Consumer Class.

10. The remainder of this declaration proceeds as follows: In Section II, I detail my professional background. In Section III, I review the relevant regulation of prescription drugs in the United States. In Section IV, I review the relevant financing and organization of prescription drugs in the United States. In Sections V and VI, I describe my method of calculating damages, the data used in my calculations, and the resulting calculations in aggregate, and separately, for the Consumer and End-Payor Classes.

11. My methodology for calculating damages is flexible. The model can accommodate factual or legal findings the jury or the Court makes for changes in the at-issue Valsartan products, varying time periods, a subset of plaintiffs' purchases (to account for different types of end-payors), and offsets.

II. QUALIFICATIONS

12. My name is Rena M. Conti. I am an Associate Professor of Markets, Public Policy and Law in the Questrom School of Business at Boston University and an Academic Affiliate of Greylock McKinnon Associates, a consulting and litigation support firm. Between 2006 and 2018, I was faculty at the University of Chicago. My principal research interests concern the economics of the medical care industry. My work generally examines the factors that determine spending levels and trends in medical care, including prescription drugs.

13. At Boston University, I teach two courses on strategy in biotechnology markets and a course on business analytic methods. At the University of Chicago, I taught an undergraduate- and Ph.D.-level health economics course and a master's-level course on the economics of the pharmaceutical industry. I also taught undergraduate- and master's-level courses on a variety of health policy topics, including the commercialization and regulation of biomedical technology.

14. My principal research interests focus on the economics of the healthcare industry and the markets for pharmaceuticals in particular. My research and publications have evaluated factors that impact the purchase and use of pharmaceuticals, including quality of the pharmaceutical, pricing of the pharmaceutical, availability of therapeutic alternatives, physician prescribing behaviors and incentives, insurance coverage and reimbursement and regulation. I have

published extensively on the pricing of pharmaceuticals for consumers and payers. I have also researched extensively on pharmaceuticals undergoing patent expiration and generic entry and the resulting effects on prices, spending, and utilization and the pricing, supply and quality of prescription drugs post-generic launch. Some of my work has focused on pharmaceuticals that dispensed through retail pharmacies, while other papers have focused on pharmaceuticals prescribed or used at a physician's medical practice.

15. I have over 100 research publications in peer-reviewed leading economics, health economics and health policy journals and books focusing on topics including examinations of insurer-related reimbursement and coverage issues and trends in spending, use, and pricing of pharmaceuticals. I have testified before the Senate Finance Committee on causes of ongoing pharmaceutical shortages. I have testified at hearings hosted by the FDA on various topics related to pharmaceutical entry, competition, and quality. I have given invited talks at the United States Government Accountability Office ("GAO"), the Congressional Budgetary Office ("CBO"), the Federal Trade Commission ("FTC"), the National Institutes of Health ("NIH"), and the FDA, among other governmental agencies. Between 2018 and 2020, I served as a consultant to the FDA's Office of Generic Drugs on issues related to drug quality and adequacy of supply. I was a member of the National Academy of Sciences, Engineering and Medicine's Committee on *Ensuring Patient Access to Affordable Drug Therapies*.[8] I am currently serving as an ad hoc advisor to the National Academy of Sciences, Engineering and Medicine's Committee on *Security of America's Medical Product Supply Chain*.[9]

16. I have been retained as a consultant in a number of legal proceedings as an expert in health policy and health economics. I have submitted expert testimony in off-label marketing and

[8] See National Academies of Sciences, Engineering, and Medicine, Committee on Ensuring Patient Access to Affordable Drug Therapies, "Making Medicines Affordable: A National Imperative," 2018, available at https://www nap.edu/initiative/committee-on-ensuring-patient-access-to-affordable-drug-therapies.

[9] See National Academies of Sciences, Engineering, and Medicine, Committee on Security of America's Medical Product Supply Chain, available at https://www.nationalacademies.org/our-work/security-of-americas-medical-product-supply-chain.

promotion litigation matters;[10] delayed generic entry litigation matters;[11] and a securities matter.[12] I have also submitted testimony in one other cGMP violation matter.[13] I have also submitted reports and testified in a number of other litigation matters, including cases involving allegations related to pharmaceutical sales and reimbursement securities issues. In these reports and testimonies, the topics of pharmaceutical quality, price, insurance coverage, and reimbursement and regulation have all featured prominently.

17. I received a B.A. in Philosophy (History minor) from Kenyon College in 1992 and a Ph.D. in Health Policy (Economics Track) from Harvard University in 2007. A more complete description of my qualifications is found in my Curriculum Vitae, included as Attachment A to this declaration.

18. Greylock McKinnon Associates is compensated for my time at a rate of $775 per hour. My compensation is not dependent on my opinions or on the outcome of this litigation.

19. The documents and materials I have considered in preparation of this declaration are listed in Attachment B. Should additional materials become available, I reserve the right to update my opinions as needed.

[10] *In re Neurontin Marketing, Sales Practices, and Products Liability Litigation*, United States District Court for the District of Massachusetts, MDL No. 1629, Master File No. 04-10981; *Beverly Crawford, et al. v. Forest Pharmaceuticals, Inc.*, Missouri Circuit Court, Twenty-Second Judicial Circuit, Case No. 0922-CC08347, Division No. 1.; *Beverly Crawford, et al. v. Forest Pharmaceuticals*, *Inc*., Missouri Circuit Court, Twenty-Second Judicial Circuit, Case No. 0922-CC08347, Division No. 1; *United States of America, ex rel. James Banigan and Richard Templin, et al. v. Organon USA Inc., et al.*, United States District Court for the District of Massachusetts, Case No. 1:07-cv-12153-RWZ.

[11] *In re Androgel Antitrust Litigation*, United States District Court for the Northern District of Georgia, Atlanta Division, Case No. 1:09-MD-2084-TWT; *In re Prandin Direct Purchaser Antitrust Litigation*, United States District Court for the Eastern District of Michigan, C.A. No. 2:10-cv-12141-AC-DAS; *In re Glumetza Antitrust Litigation*, Humana Action (3:20-cv-05251-WHA), United States District Court for the Northern District of California, 3:19-cv-05822-WHA; and *In re Ranbaxy Generic Drug Application Antitrust Litigation*, United States District Court for the District of Massachusetts, MDL No. 1:19-md-02878-NMG.

[12] *Robert F. Bach, et al. v. Amedisys, Inc., et al.*, United States District Court for the Middle District of Louisiana, Civil Action No. 3:10-cv-00395-BAJ-CN.

[13] *Blue Cross Blue Shield Association, et al., v. GlaxoSmithKline LLC.*, Civil Action No.13-4663-JS, United States District Court for the Eastern District of Pennsylvania.

III. INSTITUTIONAL BACKGROUND ON THE REGULATION OF THE U. S. PRESCRIPTION DRUG MARKET

20. In this section I explain that federal law, as codified by regulations of the FDA under the FDCA, mandates that prescription drugs sold into the United States pharmaceutical supply chain be produced in accordance with cGMPs and with the manufacturers' assurance that the drugs meet legal requirements for safety, and that they have the quality, purity, identity, and strength that they are represented to possess in the drug's FDA-approved label. These laws and regulations, first and foremost, impose duties on the manufacturers of FDA-approved prescription drugs to comply with and assure all consumers and payers in the prescription drug market that their products meet, at minimum, required safety and quality standards. Oversight of manufacturers' compliance with these laws and regulations and their assurance that the products are what is stated in the FDA-approved label in accordance with all applicable laws and regulations is predicated on the manufacturers' provision of accurate information to the FDA. The rationale for the imposition of these duties onto manufacturers and the FDA's strict oversight is that patients, prescribers, and third-party payers cannot test or evaluate for themselves the safety and quality of prescription drugs.[14] Products produced and sold in compliance with cGMPs and with the manufacturers' assurance that the drugs meet legal requirements for safety, and that they have the quality, purity, identity, and strength that they are represented to possess in the drug's FDA-approved label are assigned a non-zero economic value by consumers and third-party payers. Conversely, prescription drugs that are adulterated and misbranded have no economic value, they are worthless.

A. Pharmaceutical manufacturers' compliance with cGMPs is the foundation upon which prescription drugs are sold and purchased in the United States.

21. Pharmaceutical manufacturers' compliance with cGMPs in manufacturing prescription drugs and assurances that prescription drugs meet legal requirements for safety, and that they have the quality, purity, identity, and strength that they are represented to possess on the FDA approved label as required by law and applicable regulations provides the foundation upon which prescription drugs are sold and purchased in the United States. If a prescription drug is available

[14] See P.M. Danzon and E.L. Keuffel, "Regulation of the Pharmaceutical-Biotechnology Industry," *Economic Regulation and Its Reform: What Have We Learned?*, ed. N.L. Rose, University of Chicago Press: Chicago, IL, 2005, pp. 407-84.

for sale in the United States, patients and third-party payers rely on the manufacturer's assurance that the drug has the safety, identity, purity, potency, and quality it purports to have, as required by law and applicable regulations.[15]

22. Reasons that the FDA deems a drug "adulterated"[16] include, but are not limited to: if it contains any filthy or decomposed substance (FDCA § 501(a)(1), 21 U.S.C. § 351(a)(1)); if it is prepared, packed, or held under unsanitary conditions (FDCA § 501(a)(2)(A), 21 U.S.C. § 351(a)(2)(A)); if methods used do not conform to good manufacturing practices (FDCA § 501(a)(2)(b), 21 U.S.C. § 351(a)(2)(b), 21 CFR Parts 210 & 211);[17] if its container is composed of a poisonous or deleterious substance that may cause contents to be injurious to health (FDCA § 501(a)(3), 21 U.S.C. § 351(a)(3)); if it contains an unsafe coloring additive (FDCA § 501(a)(4), 21 U.S.C. § 351(a)(4)); if its strength, quality, or purity falls below compendial standards (FDCA § 501(b), 21 U.S.C. § 351(b)); if its strength or purity falls below what it purports to possess (FDCA § 501(c), 21 U.S.C. § 351(c)); or if it is mixed or packaged to reduce quality or strength (FDCA § 501(d), 21 U.S.C. § 351(d)).

23. Reasons that the FDA deems a drug as "misbranded" include, but are not limited to: its label being false or misleading (FDCA § 502(a), 21 U.S.C. § 352(a)); its label failing to disclose all active and inactive ingredients and their quantities (FDCA § 502(e), 21 U.S.C. § 352, 21 C.F.R. § 201.10(c)(2)); its label failing to disclose any potential side effects (FDCA § 502(n), 21 U.S.C. § 352(n)) and/or list other warnings (FDCA § 502(f), 21 U.S.C. § 352(f)).

24. Manufacturers and other parties are prohibited from introducing "adulterated" or "misbranded" drugs into interstate commerce in the United States.[18] This is to prevent payers from purchasing a product and consumers from consuming a product that does not have the

[15] Plaintiffs' Counsel has informed me that state laws also exist related to the issues of pharmaceutical cGMPs, pharmaceutical labeling, adulteration, and misbranding.

[16] See 21 U.S.C. § 351.

[17] See Food Drug Law Institute's Workshop, "Introduction to Drug Law and Regulation: Regulation of Drug Manufacturing," November 8-9, 2010, at p. 15, available at https://www.alston.com/-/media/files/insights/events/2010/11/introduction-to-drug-law-and-regulation-how-the-go/files/cirotta-and-burgess-11-9-10--regulation-of-drug-ma/fileattachment/cirotta-and-burgess-11-9-10--regulation-of-drug-ma.pdf.

[18] 21 U.S.C. § 331(a)-(c).

manufacturer's assurance of its safety, identity, purity, potency, and quality it purports to have on its FDA-approved label and as required by law and applicable regulations.

25. Since its inception, it has been the FDA's central mission to protect American consumers from adulterated or misbranded prescription drugs. The agency's regulatory functions began with the passage of the 1906 Pure Food and Drugs Act, a law that prohibited interstate commerce in adulterated and misbranded food and drugs.[19] According to the FDA website, the law was enforced by the Bureau of Chemistry in the Department of Agriculture, which became the FDA in 1930.[20]

26. The FDA explains the rationale for its central focus on protecting consumers from adulterated and misbranded drugs on its webpage (titled "Promoting Safe and Effective Drugs for 100 Years") as follows: "At the turn of the 20th century, there were no federal regulations to protect the public from dangerous drugs. 'It was a menacing marketplace filled with products such as William Radam's Microbe Killer and Benjamin Bye's Soothing Balmy Oils to cure cancer,' says John Swann, Ph.D., a historian at the Food and Drug Administration in Rockville, Md. 'Products like these were, at minimum, useless remedies that *picked the pocket of the user*, but *they could also be downright harmful*.'"[21] I emphasize the text in italics because the FDA's statement underscores the harms from adulterated or misbranded products are twofold: first, economic losses from purchasing products that are adulterated and misbranded and second, the possibility of clinical harm from consumption of adulterated and misbranded products.

27. Throughout the past several decades, the United States Congress has continued to act to ensure the safety of the United States prescription drug market, including by seeking to remove adulterated and misbranded products from the United States market. In these actions, Congress and the FDA relied on the assurances of the drug's approved manufacturer in the United States as to the products' safety, efficacy, quality, and production in compliance with law and applicable regulations. For example, in the 1980s, Congress recognized that some entities not

[19] FDA, "Part I: The 1906 Food and Drugs Act and Its Enforcement," April 24, 2019, available at https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-i-1906-food-and-drugs-act-and-its-enforcement.

[20] FDA, "Promoting Safe & Effective Drugs for 100 Years," March 27, 2018, available at https://www.fda.gov/AboutFDA/History/ProductRegulation/ucm2017809 htm.

[21] *Ibid.,* emphasis added.

subject to United States law were importing counterfeit products as well as improperly handling and storing products, including counterfeit birth control pills, and selling them as FDA-approved prescription drugs. Congress viewed these types of activities as posing 'significant risks to American consumers.' Therefore, in 1987, Congress passed the Prescription Drug Marketing Act (PDMA), which, among other things, strengthened oversight of domestic wholesalers and added the "American goods returned" provision to the FD&C Act[22] which prohibits any entity except a drug's approved manufacturer from importing into the United States a prescription drug that was originally manufactured in the United States and then sent abroad.

28. To further prevent payers from purchasing a product and consumers from consuming a product that does not have the manufacturer's assurance of its safety, identity, purity, potency, and quality it purports to have on its FDA-approved label and as required by law and applicable regulations, the FDA introduced the concept of cGMPs into the regulation of prescription drugs. From the agency's perspective, cGMP principles include: "(1) *Quality, safety, and effectiveness* must be *designed and built into a product*; (2) *Quality cannot be inspected or tested into a finished product*; and (3) Each step of the manufacturing process must be controlled to maximize the likelihood that the finished product will be acceptable."[23] In this way, the production of prescriptions drugs is viewed as inseparable from manufacturer's assurance of prescription drugs' safety, identity, purity, potency, and quality they purport to have on its FDA-approved label and as required by law and applicable regulations.

29. The Code of Federal Regulations covering rules under the purview of the FDA is Title 21, which interprets the Federal Food, Drug and Cosmetic Act and related statutes, including the Public Health Service Act. The statues include several sections on pharmaceutical and drug quality-related regulations. According to the FDA "cGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations provide the minimum guidelines necessary to make sure that a product is safe for use, and that it has the ingredients and strength it

[22] U.S. Department of Health and Human Services, "HHS Task Force on Drug Importation," December 2004, pp. VII-VIII, available at http://www.safemedicines.org/wp-content/uploads/2018/03/HHS-Report1220.pdf.

[23] FDA, "Process Validation: General Principles and Practices," pp. 3-4, available at https://www.fda.gov/files/drugs/published/Process-Validation--General-Principles-and-Practices.pdf.

claims to have."[24] FDA rules also reaffirm the duties manufacturers have to provide assurance that prescription drugs are safe and manufactured according to cGMP: "The approval process for new and generic drug marketing applications includes a review of the manufacturer's compliance with the cGMPs. FDA assessors and investigators determine whether the firm has the necessary facilities, equipment, and ability to manufacture the drug it intends to market."[25] From time to time, the FDA has updated and clarified its cGMP regulations for prescription drug manufacturers.[26] Today, the FDA enforces prescription drug supply regulations that include, but are not limited to, requirements that manufacturers assure that they continuously meet quality manufacturing standards and comply with regulatory oversight, including routine information sharing and engagement with regulators. According to the FDA, "the drug review process in the United States is recognized worldwide as the gold standard. Drugs must undergo a rigorous evaluation of safety, quality, and effectiveness before they can be sold."[27]

30. It is the responsibility of manufacturers to ensure products meet minimum thresholds of safety, quality, and purity, and contain the ingredients and strength claimed to have on the FDA-approved label. Oversight activities by regulators in the United States are fundamentally predicated on the accuracy of information provided by the manufacturers and their assurances of the safety, quality, and efficacy of the product. FDA rules reaffirm the minimum duties manufacturers have to provide assurance that prescription drugs are safe and manufactured according to cGMP.

31. The FDA recognizes the public's need to rely on prescription drug manufacturers' ongoing compliance with regulatory requirements and manufacturers' representations of such compliance: "Pharmaceutical quality is the foundation that allows patients and consumers to

[24] FDA, "Current Good Manufacturing Practice (CGMP) Regulations," available at https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations.

[25] *Ibid.*

[26] cGMPs are now codified at 21 CFR parts 210 through 226. For a timeline of major revisions, see Food Drug Law Institute's Workshop, *op. cit.*, p. 20.

[27] FDA, "Promoting Safe & Effective Drugs for 100 Years," March 27, 2018, available at https://www.fda.gov/AboutFDA/History/ProductRegulation/ucm2017809 htm.

have confidence in the safety and effectiveness of their medications."[28] Consequently, in a prescription drug is available for sale in the United States prescription drug market, consumers should expect these drugs to meet or exceed minimum safety and quality standards and contain the ingredients and strength claimed to have on the FDA-approved label when consuming an FDA-approved prescription drug. In addition, payers should expect prescription drugs to meet or exceed minimum safety and quality standards and contain the ingredients and strength claimed to have on the FDA-approved label when paying for an FDA-approved prescription drug.

32. Consumer and payer confidence in the safety and quality of prescription drugs sold in the United States market is reaffirmed by the substantial penalties that can be levied on prescription drug manufacturers for cheating the system.[29]

33. Contemporary policy efforts reaffirm that a pharmaceutical manufacturer's compliance with these laws and regulations provides the foundation for the legitimate supply of prescription drugs in the United States market. For example, in 2013, Congress passed the Drug Quality and

[28] FDA, "Pharmaceutical Quality Resources," April 26, 2018, available at https://www fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/default htm.

[29] See H. Banuelos, "More Scrutiny for cGMP Violations, DOJ to pursue enforcement," *Contract Pharma,* May 6, 2013, available at https://www.contractpharma.com/issues/2013-05/view_fda-watch/more-scrutiny-for-cgmp-violations; United States Department of Justice, "Deputy Assistant General Maame Ewusi-Mensah Frimpong Speaks at the 2013 CBI Pharmaceutical Compliance Congress," January 29, 2013, available at https://www.justice.gov/opa/speech/deputy-assistant-attorney-general-maame-ewusi-mensah-frimpong-speaks-2013-cbi; and United States Department of Justice, "GlaxoSmithKline to Plead Guilty & Pay $750 Million to Resolve Criminal and Civil Liability Regarding Manufacturing Deficiencies at Puerto Rico Plant," October 26, 2010, available at https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-pay-750-million-resolve-criminal-and-civil-liability-regarding.

Since 1991, the FDA has maintained its own criminal investigation and law enforcement office, the Office of Criminal Investigations ("OCI"). The OCI is "empowered to conduct and coordinate criminal investigations of violations of the Federal Food, Drug, and Cosmetic Act, the Federal Anti-Tampering Act, other related acts, and applicable violations of USC 18 (Crimes and Criminal Procedures)," and "protects the American public by conducting criminal investigations of illegal activities involving FDA-regulated products, arresting those responsible, and bringing them before the Department of Justice for prosecution." See FDA, "Criminal Investigations," May 30, 2018, available at https://www.fda.gov/ICECI/CriminalInvestigations/default htm and FDA, "About OCI," May 22, 2018, available at https://www.fda.gov/ICECI/CriminalInvestigations/ucm550316.htm.

Since 1993, the OCI has investigated thousands of schemes involving a broad range of criminal conduct, including but not limited to the distribution of misbranded, counterfeit, and unapproved medical products. The OCI's current stated priorities include the identification of "[b]reaches in the legitimate medical supply chain by individuals and organizations dealing in unapproved, counterfeit, and substandard medical products" and "Criminal conduct that prevents the FDA from being able to properly regulate. This includes false statements to the FDA during the regulatory process and obstruction of justice." See FDA, "Investigative Priorities," June 21, 2017, available at https://www fda.gov/ICECI/CriminalInvestigations/ucm546093 htm.

Security Act amending the FDCA to increase standards for assessing quality manufacturing of prescription drugs sold in the United States and to reduce opportunities for adulterated or counterfeit drugs to enter the United States supply chain.[30] Title II of the bill, the Drug Supply Chain Security Act, colloquially called 'Track and Trace,' established increased requirements to facilitate the tracing of prescription drug products through the pharmaceutical supply distribution chain.[31] Pharmaceutical manufacturers and their trade organizations largely supported these efforts, arguing that ensuring the quality of prescription drugs sold in the United States is critical to public safety.[32]

34. Manufacturer compliance with laws and regulations assuring consumers and payers of the safety and quality of prescription drugs sold in the United States prescription drug market has also been part of the public debate about whether to allow prescription drugs to be imported from other countries where they are legally sold at lower prices.[33] The main concern regarding this practice is that importation is risky and would endanger American consumers by exposing them to fake, substandard and contaminated drugs.[34] The Kaiser Family Foundation summarizes concerns over importation in the following way: "the drug distribution network for prescription drugs in the United States is a 'closed' system that provides the American public with multiple

[30] See "Public Law 113-54, Drug Qualities and Securities Act," November 27, 2013, available at https://www.congress.gov/113/plaws/publ54/PLAW-113publ54.pdf.

[31] *Ibid.* See also FDA, "Drug Supply Chain Security Act (DSCSA)," May 11, 2018, available at https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/.

[32] See R. Robinson, "Track and Trace: Preparing for DSCSA Implementation," January 2015, available at http://www.pharmavoice.com/article/track-trace-preparing-dscsa-implementation/ ("Mr. Sanchez at Virtus [Pharmaceuticals] says meeting compliance requirements is not the only driving factor behind implementing a track and trace system, there are many other benefits, for example, a big one is safety… 'Quality and safety are our top priorities at Virtus… This system will help us better align our quality processes. As our process develops and evolves it will enhance our systems so that we can be properly prepared in case any issues arise.'") See also Healthcare Distribution Alliance, "Pharmaceutical Traceability," available at https://www.healthcaredistribution.org/issues/pharmaceutical-traceability (highlighting that the DSCSA "clarified and consolidated supply chain regulations, increasing the efficiency and safety of the supply chain," "strengthened distributor licensure standards across the United States," and "established new processes for identifying suspect and illegitimate products in the supply chain.")

[33] See "Public Law 108-173, Medicare Prescription Drug, Improvement, and Modernization Act of 2003," December. 8, 2003, at section 1121-1123, available at https://www.congress.gov/108/plaws/publ173/PLAW-108publ173.pdf.

[34] See L. McGinley, "Four former FDA commissioners denounce drug importation citing dangers to consumers," *Washington Post*, March 17, 2017, available at https://www.washingtonpost.com/news/to-your-health/wp/2017/03/17/four-former-fda-commissioners-denounce-drug-importation-citing-dangers-to-consumers/?noredirect=on&utm_term=.9bc5f9a6ffcd.

levels of protection against receiving unsafe or poor quality medications. Importation…would create an opening in this closed system that would increase the opportunity for counterfeit, substandard, or unapproved products to enter the supply chain, introducing additional risks to American consumers."[35]

35. Similarly, when the United States has experienced supply shortages of some prescription drugs in recent decades, the FDA has worked to reduce supply disruptions and, at times, has identified alternative sources of selected drug supply.[36] In these circumstances, the FDA has maintained the United States' pharmaceutical supply chain as the 'gold standard'. The FDA requires manufacturers of drugs in short supply to comply with laws and regulations and provide the required assurances of safety, quality and that the product is what is stated on the FDA-approved label.[37]

36. These efforts to affirm, and in some cases increase, manufacturers' assurance of product safety and quality in the United States pharmaceutical supply chain have been supported by pharmaceutical manufacturers[38] to protect the legitimacy of their FDA-approved products and, consequently, their ability to sell and profit from prescription drugs in the United States market.

37. Moreover, manufacturer compliance with these laws and regulations assuring the safety and quality of prescription drugs sold in the United States market is foundational to the payment for prescription drugs by third-party payers. Third-party payers make prescription drug coverage and purchasing decisions based on manufacturers' compliance with all applicable safety and

[35] Kaiser Family Foundation, "10 FAQs on Prescription Drug Importation," July 28, 2012, available at https://www.kff.org/medicare/issue-brief/10-faqs-on-prescription-drug-importation/.

[36] FDA, "Frequently Asked Questions about Drug Shortages: What can FDA do to address drug shortages?" updated November 13, 2020, available at https://www fda.gov/drugs/drug-shortages/frequently-asked-questions-about-drug-shortages#q5. See also, FDA, "Strategic Plan for Preventing and Mitigating Drug Shortages," October 2013, available at https://www fda.gov/media/86907/download.

[37] See G. Harris, "Shipments From Abroad to Help Ease Shortage of Two Cancer Drugs," *New York Times,* February 21, 2012, available at https://www.nytimes.com/2012/02/22/health/policy/fda-approves-imports-amid-shortage-of-2-cancer-drugs html; R.M. Conti, "Secretive Contract Manufacturing Arrangements Complicate Solutions to Shortages of Generics," *The Cancer Letter*, January 3, 2014, available at https://cdn.cancerhistoryproject.com/media/2014/01/10000000/TCL40-01; and Pharmaceutical Research and Manufacturers of America, "Drug Shortages & Supply Chain Info," available at https://www.phrma.org/advocacy/safety/drug-shortages-supply-chain.

[38] Pharmaceutical Research and Manufacturers of America, "The biopharmaceutical industry's commitment to quality," February 11, 2016, available at https://catalyst.phrma.org/the-biopharmaceutical-industrys-commitment-to-quality.

quality laws and regulations governing the sale of FDA-approved prescription drugs.[39] In this matter, the end-payors relied on the Defendants to manufacture and sell prescription drugs that comply with all laws and regulations so that each at-issue Valsartan product had the safety, identity, purity, potency, and quality that its label represented it possessed.[40] Similarly, patients who filled prescriptions for at-issue Valsartan products had no choice but to rely on the manufacturers' assurance of safety, efficacy and compliance with all laws and regulations. This is due to the asymmetrical nature of knowledge regarding pharmaceutical safety and quality which I discuss below.

38. Finally, manufacturers compliance and assurance that their products meet *at minimum* all applicable safety and quality laws and regulations governing the sale of FDA-approved prescription drugs is essential to a generic drug product's listing in the Orange Book;[41] indeed, it is essential to the very status of generic drugs, including the at-issue Valsartan products, as generic. The Orange Book lists all drugs approved by the FDA and their therapeutic equivalents (if any). The FDA awards generic status to those drugs that the manufacturer demonstrates are therapeutically equivalent to an already-approved brand medication. The requirements for therapeutic equivalence are clearly stated in the Orange Book preface: "FDA classifies as therapeutically equivalent those drug products that meet the following general criteria: (1) they are approved as safe and effective; (2) they are pharmaceutical equivalents in that they (a) contain identical amounts of the identical active drug ingredient in the identical dosage form and route of administration, and (b) meet compendial or other applicable standards of strength, quality, purity, and identity; (3) they are bioequivalent in that (a) they do not present a known or potential bioequivalence problem, and they meet an acceptable in vitro standard, or (b) if they do present such a known or potential problem, they are shown to meet an appropriate bioequivalence standard; (4) they are adequately labeled; and (5) they are manufactured in

[39] *See* Declaration of Humana Inc., *in this matter*, October 27, 2021, at ¶ 2, "When making the decision whether a drug's cost will be covered, Humana relies on manufacturers' direct or indirect representations that their products are in compliance with FDA regulations, are not adulterated or misbranded, are free from defects, and are fit for their intended purpose."

[40] *Ibid.*

[41] FDA, Orange Book Preface, available at https://www fda.gov/drugs/development-approval-process-drugs/orange-book-preface.

compliance with Current Good Manufacturing Practice regulations."[42] Finally, although the inactive ingredients of generic drug products are permitted to vary more compared to active ingredients from those of their brand counterparts, they must be shown not to affect "the safety or efficacy of the proposed drug product"[43] in order to receive approval and be listed in the FDA Orange Book.

B. From an economic perspective, adulterated and misbranded prescription drugs have no economic value, they are worthless.

39. From an economic perspective, there exists substantial asymmetric information about the safety and quality of prescription drugs between the manufacturers themselves and those who prescribe, purchase, consume, and pay for these products. When such substantial asymmetric information about product attributes exists, manufacturers have an economic incentive to generate revenue by selling a product that is worthless (or even harmful) unless legal duties and other constraints prevent them from doing so.

40. In addition, third-party payers continuously assess whether and which prescription drug treatments might provide their members benefit and value to treat medical conditions and symptoms. The assurance of safety and quality by the manufacturers of prescription drugs is foundational to third-party payers' decision making. In other words, in the United States prescription drug market, insurers do not monitor drug manufacturers' compliance with laws and regulations related to safety and quality; that is not their job. Instead, they presume that drug manufacturers are in compliance with all applicable laws and regulations related to safety and quality, that the drugs are not adulterated or misbranded and that the FDA and other regulatory agencies have monitored the manufacturers' efforts to ensure compliance, otherwise they would not be placed into the stream of commerce. There is no insurer demand for non-safety and quality compliant, adulterated, and misbranded drugs.

41. Accordingly, the FDA recognizes the public's need to rely on prescription drug manufacturers' compliance with regulatory requirements and manufacturers' representations of

[42] FDA, Orange Book Preface, available at https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface.

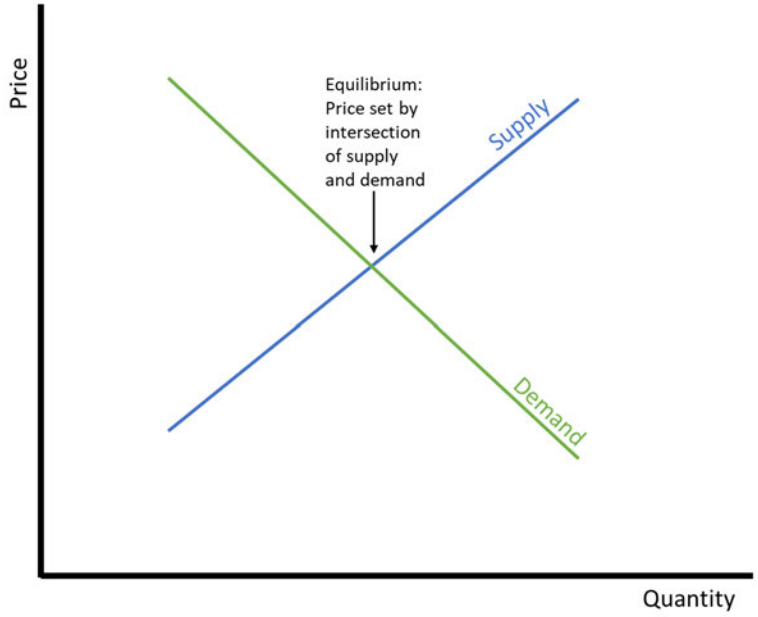
[43] 21 CFR 314.94(9)(ii).

such compliance: "Pharmaceutical quality is the foundation that allows patients and consumers to have confidence in the safety and effectiveness of their medications."[44]

42. Federal law establishes that non-safety and quality compliant, adulterated, and misbranded prescription drugs are not legitimate consumer products and cannot be lawfully sold or distributed for sale. In effect, prescription drugs that do not meet the foundational standard of safety and quality manufacturing have no economic value. Thus, in this matter, because the drug manufacturers produced and sold non-safety and quality compliant adulterated and misbranded drugs, plaintiffs paid for illegitimate products that have no economic value.

43. According to economic theory, for a consumer product to have economic value, demand for the product must exist and supply must be allowed to meet demand. See Figure 1, which illustrates the basic economics of supply, demand, and pricing.

Figure 1
Supply and Demand

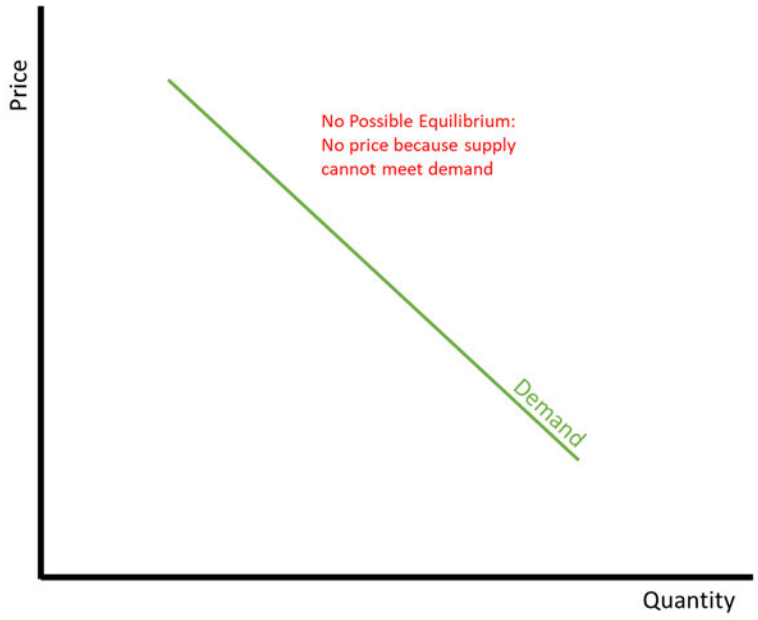


44. In the United States, the regulation of prescription drugs prohibits the sale of products that are non-compliant with safety and quality standards; such products are adulterated and misbranded. Consequently, if a prescription drug is available for sale in the United States drug market, its purchase is predicated on its safety and quality of its manufacturing, as assured by the

[44] FDA, "Pharmaceutical Quality Resources," *op. cit.*

manufacturer and overseen by government regulators. Conversely, non-safety and quality compliant prescription drugs should not be available for sale in the United States drug market and have no economic value. Therefore, there is no legitimate supply curve for such drugs. Under these circumstances, there is no equilibrium between the demand for safety and quality compliant prescription drugs and the supply of non-compliant drugs. As a result, there is no economically determinable price for non-compliant drugs. See Figure 2.

Figure 2
Demand with No Legitimized Supply



45. Furthermore, assigning a non-zero value to non-safety and quality compliant products is perverse. To do so would be to incentivize and legitimize cheating and non-compliance by manufacturers and other members of the United States pharmaceutical supply chain, and would undermine the substantial investments made by the government and private parties to protect the wellbeing of American patients. This would be a fundamental departure from mechanisms described in the preceding section designed to protect the American public.

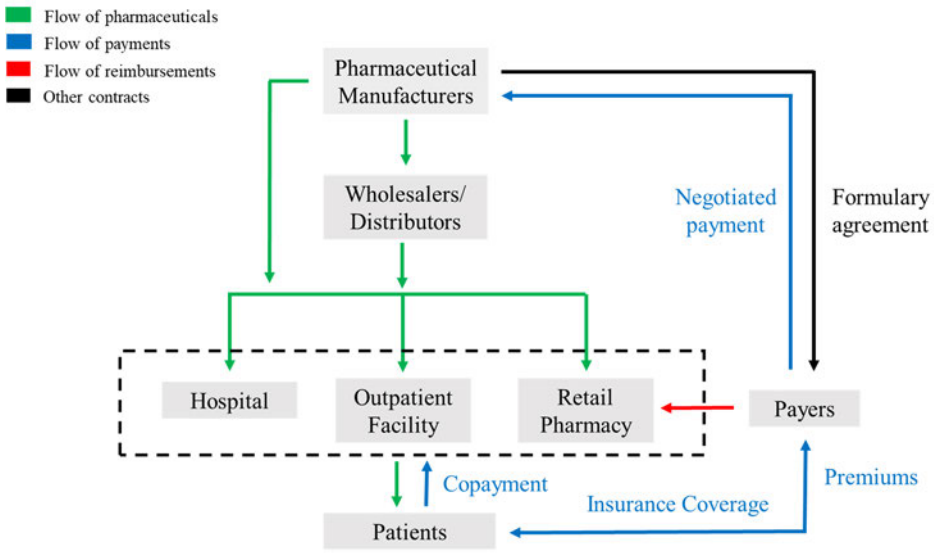
46. I conclude based on basic economic principles and my expertise in how pharmaceutical markets are established and function in the United States that non-complaint, adulterated and misbranded prescription drugs have no economic value.

IV. INSTITUTIONAL BACKGROUND ON THE ORGANIZATION AND FINANCING OF THE U. S. PRESCRIPTION DRUG MARKET

47. The organization and financing of prescription drugs involves numerous participants that need to be identified and whose roles must be understood when assessing the United States pharmaceutical market. The demand for prescription drugs, such as the at-issue Valsartan products, is semi-derived; that is, the demand for at-issue Valsartan products is driven in part by physicians who prescribe them in the management of their patients' illness. Demand for prescription drugs is also influenced by the policies of third-party payers who pay in part for prescription drugs dispensed to their members and other parties in the United States prescription drug market who enable the purchase and sale of prescription drugs. Consequently, demand for the at-issue Valsartan products is impacted by physicians treating their patients, and the pharmacists, wholesale distributors, and payers who work to enable the purchase of the at-issue Valsartan products by patients.

48. **Figure 3** presents an illustrative pharmaceutical supply chain, with green and blue arrows between participants indicating the flow of pharmaceuticals and dollars, respectively. A description of each of the participants follows.

Figure 3
Pharmaceutical Supply Chain



49. *Pharmaceutical Manufacturers* – Pharmaceutical manufacturers, such as the Defendant Manufacturers in this matter, produce and commercialize prescription drugs to address patient

needs.[45] Pharmaceutical manufacturers and the pharmaceuticals they sell are subject to extensive safety and quality regulations in the United States market described in detail above.

50. *Wholesalers/Distributors* – Wholesaler/distributors (e.g., AmerisourceBergen, Cardinal Health, McKesson Corporation) serve as intermediaries that purchase pharmaceuticals from pharmaceutical manufacturers and distribute them to a variety of healthcare providers.[46] Given that the at-issue Valsartan products are small molecule orally formulated generic drugs, the majority of purchases are made by pharmacies from wholesalers/distributors.[47]

51. *Physicians/Hospitals/Outpatient Facilities/Pharmacies* –Physicians (and other prescribers such as Nurse Practitioners and Physicians Assistants) choose whether and what prescription drug to prescribe to patients. Hospitals, Outpatient Facilities and Pharmacies dispense prescribed drugs to patients at the recommendation of physicians (and other prescribers such as Nurse Practitioners and Physicians Assistants). Hospitals, Outpatient Facilities and Pharmacies receive pharmaceuticals from wholesaler/distributors or directly from the manufacturers.

52. *Payers* – Third party payers (TPPs) include commercial insurers (e.g., Blue Cross Blue Shield) and public insurers (i.e., Medicare and Medicaid) who provide medical and pharmaceutical insurance, and reimburse pharmacies when their members (the patients) are

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[45] L. Ellis, "Snapshot of the American Pharmaceutical Industry," Harvard T.H. Chan School of Public Health, July 14, 2016, available at https://www hsph.harvard.edu/ecpe/snapshot-of-the-american-pharmaceutical-industry/.

[46] E.R. Berndt and J.P. Newhouse, "Pricing and Reimbursement in U.S. Pharmaceutical Markets," NBER Working Paper No. 16297, August 2010 ("Berndt and Newhouse (2010)"), at p. 7; and R. Britt, "'Big Three' Pharma Distributors Post Sharp Gains," *MarketWatch*, September 15, 2010, available at https://www.marketwatch.com/story/big-3-pharma-distributors-post-sharp-gains-2010-09-15.

[47] Mylan and Teva have both reported their top customers in their 10-K filings. Teva shows its two largest customers to be McKesson Corporation and AmerisourceBergen Corporation in 2015-2017, accounting for at least 30% of total sales. Mylan shares these same top two customers for 2015-2017 and names its third biggest, Cardinal Health, Inc. These three wholesalers also account for about 30% of all Mylan sales in the three years reported. It should be noted that these percentages are global, not just for the United States, and they are taken across the companies' portfolios, rather than specific to Valsartan. The United States market makes up about 40% of the total revenue for both Mylan and Teva. See Teva Form 10-K, 2017, pp. 188-189, available at https://www.sec.gov/Archives/edgar/data/818686/000119312518039076/d529462d10k htm; and Mylan Form 10-K, 2017, pp. 22 and 145, available at https://sec.report/Document/0001623613-18-000010/myl10k_20171231xdoc.htm.

Other Defendant Manufacturers do not publicly publish similar breakdowns of their customers, but a recent report from Deloitte Consulting finds that distributors handle 92% of pharmaceuticals sales in the United States (Deloitte and the Healthcare Distribution Alliance, "The role of distributors in the US health care industry: 2019 report," 2019, p. 3, available at https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-hda-role-of-distributors-in-the-us-health-care-industry.pdf.

dispensed a prescription at a pharmacy.[48] Payers make a single payment to the pharmacy that entails the reimbursement price of the drug and a dispensing fee.[49] Most TPPs maintain their own lists of covered pharmaceuticals ("formularies") which is overseen by a Pharmacy and Therapeutics ("P&T") committee or delegate this responsibility to a pharmacy benefit manager (PBM). P&T committee members often include physicians, pharmacists, nurses, administrators, quality-improvement managers, and other professionals.[50] The foundation of prescription drug coverage by TPPs is the product's FDA approval for sale in the United States prescription drug market and consequently the manufacturers' assurance of safety, efficacy and compliance with all laws and regulations. According to Humana, one of these TPPs, "[w]hen making the decision whether a drug's cost will be covered, Humana relies on manufacturers' direct or indirect representations that their products are in compliance with FDA regulations, are not adulterated or misbranded, are free from defects, and are fit for their intended purpose."[51]

53. *Patients* – Patients purchase a prescription drug at the pharmacy. Patients may be required by their insurer to pay some portion of the cost/charges for the dispensed prescription drug in the form of copayments, coinsurance, and deductibles. TPPs typically pay the majority of the cost/charges for prescription drugs when the patient is insured.

54. In summary, the at issue Valsartan products are available to be sold to patients who have a prescription for the product from a treating licensed physician. The majority of purchases are made by patients from pharmacies who in turn purchased the at-issue Valsartan products from

[48] Berndt and Newhouse (2010), p. 7.

[49] Morgan Lewis, "Medical Reimbursement for Drugs and Devices," Emerging Life Sciences Companies, second edition, Chapter 18, pp. 139-148 at p.140, available at https://www.morganlewis.com/topics/entrepreneurresources/~/media/files/Special-Topics/ERH_pubs/ERH_MedicareReimbursementForDrugsAndDevices_ELSCDeskbook. See also, Academy of Managed Care Pharmacy, "Pharmaceutical Payment Methods, 2013 Update," available at https://www.amcp.org/sites/default/files/2019-03/Full-Pharmaceutical-Guide-(3.0).pdf.

[50] American Society of Health-System Pharmacists, "ASHP statement on the pharmacy and therapeutics committee and the formulary system," Am J Health-Syst Pharm, 2008, available at https://www.ashp.org/-/media/assets/policy-guidelines/docs/statements/pharmacy-and-therapeutics-committee-and-formulary-system.ashx; American Society of Health-System Pharmacists, "ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System," American Journal of Health Systems Pharmacy, 78(10), May 2021, pp. 907-918, available at https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/gdl-pharmacy-therapeutics-committee-formulary-system.ashx; and D. Shulkin, "Reinventing the Pharmacy and Therapeutics Committee," *Pharmacy and Therapeutics*, November 2012, 37(11), pp. 623-624, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3498992/.

[51] See Declaration of Humana Inc., *in this matter*, dated October 27, 2021, at ¶ 2.

wholesale distributors. Payment for the at-issue Valsartan products is a single payment intended to cover the cost of the drug and a dispensing fee. When the patient is insured, the majority of the costs of a dispensed prescription is paid by a third-party payer and patients may be required to pay some out of pocket costs through deductibles, coinsurance and copayments. FDA approval is the pre-condition for third party payer coverage and reimbursement of prescription drugs.

V. CALCULATION OF MANUFACTURER AND RETAILER DAMAGES

55. The standard empirical methods I use to calculate plaintiff damages are described in this section. My plaintiff damage calculations related to the alleged at-issue Defendant Manufacturer and Defendant Retailer activities employ IQVIA Xponent data and Defendant Retailer pharmacy claims data that reflect payments made for the at-issue Valsartan products at the point of sale.

56. The "economic price" of the alleged fraud committed by the Defendants Manufacturers and Retailers is the price of each at-issue prescription sold and paid for by End-Payor and Consumers Class members at the point of sale.[52] It is calculated as the total dollar amount paid for the adulterated and misbranded at-issue Valsartan products from January 1, 2012 until the at-issue Valsartan products were recalled in 2018 and 2019.[53]

57. Consequently, to arrive at an estimate of economic damages, I total the quantity of at-issue Valsartan products purchased by class plaintiffs and multiply it by the cost incurred for the at-issue Valsartan products.

A. Overview:

58. Plaintiffs' Counsel have asked me to calculate damages for four different theories of liability against the Manufacturer Defendants and two different theories of liability and one theory of unjust enrichment against the Defendant Retailers. For each of these theories, Plaintiffs' Counsel provided me with subgroupings of Defendants by state.[54] Details on each of

[52] According to the theory of harm, damages occurred at the point of sale. I do not consider offsets such as rebates when calculating damages again the Manufacturer and Retailer Defendants since these do not occur at the point of sale.

[53] See footnote 3, above.

[54] "Valsartan Consumer Class Definitions and Exclusions" and "Valsartan TPP Class Definitions and Exclusions."

these subgroupings are provided in Attachments C through I of this declaration. The different theories of liability and unjust enrichment that I have been asked to calculate are:

- Manufacturer Express Warranty Theory of Liability.[55]
- Manufacturer Implied Warranty Theory of Liability.[56]
- Manufacturer Common Law Fraud Theory of Liability.[57]
- Manufacturer Consumer Protection Act Claims Theory of Liability.[58]
- Retailer Implied Warranty Theory of Liability.[59]
- Retailer Consumer Protection Act Claims Theory of Liability.[60]
- Retailer Theory of Unjust Enrichment.[61]

59. Plaintiffs' Counsel have asked me to calculate Consumer Class damages for both Manufacturer and Retailer theories of liability and unjust enrichment, and to calculate End-Payor Class damages for only the Manufacturer theories of liabilities. I have not been asked to calculate End-Payor Class damages for the Retailer theories of liability or unjust enrichment.[62]

B. Methodology for the calculation of liability damages

60. Expenditures by plaintiffs for the at-issue Valsartan products can be expressed as the product of price and quantity over the relevant time period of the alleged misconduct. Specifically, for any product *d*, at any time period *t*:

$$\text{Total Expenditures}_{d,t} = Q_{d,t} * P_{d,t} \quad (1)$$

[55] Details and state-level damages for this theory of liability are included in Attachment C.

[56] Details and state-level damages for this theory of liability are included in Attachment D.

[57] Details and state-level damages for this theory of liability are included in Attachment E.

[58] Details and state-level damages for this theory of liability are included in Attachment F.

[59] Details and state-level damages for this theory of liability are included in Attachment G.

[60] Details and state-level damages for this theory of liability are included in Attachment H.

[61] Details and state-level damages for this theory of liability are included in Attachment I.

[62] Some claims fall into multiple categories of the different theories of liability and unjust enrichment. I can calculate deduplicated total damages across any combination of these different theories, if needed.

Where:

$Q_{d,t}$ = the quantity of product *d*, purchased at time period *t*.

$P_{d,t}$ = the price of product *d*, purchased at time period *t*.

61. Because I have been asked to calculate these expenditures for both the Consumer and End-Payor Classes, I adjust formula (1) to calculate total expenditures for the Consumer and End-Payor Classes separately. Specifically, for the Consumer Class, total expenditures for any product *d*, at any date *t* can be expressed as:

$$\text{Consumer Class Expenditures}_{d,t} = (Q_{d,t,Cash} * P_{d,t,Cash}) + (Q_{d,t,Copay} * P_{d,t,Copay}) \quad (2)$$

Where:

$Q_{d,t,Cash}$ = the quantity of product *d*, purchased at time period *t*, for uninsured cash-paying purchasers.

$P_{d,t,Cash}$ = the full price of product *d*, purchased at time period *t*, for uninsured cash-paying purchasers.

$Q_{d,t,Copay}$ = the quantity of product *d*, purchased at time period *t*, for insured, copay- or coinsurance-paying purchasers.

$P_{d,t,Copay}$ = the copay/coinsurance price of product *d*, purchased at time period *t*, for insured, copay- or coinsurance-paying purchasers.

Similarly, the End-Payor Class Expenditures for any product *d*, at any date *t* can be expressed as:

$$\text{TPP Class Expenditures}_{d,t} = (Q_{d,t,TPP} * P_{d,t,TPP\_Total}) - (Q_{d,t,TPP} * P_{d,t,TPP\_Copay}) \quad (3)$$

Where:

$Q_{d,t,TPP}$ = the quantity of product *d*, purchased at time period *t*, for TPP class purchasers.

P_{d,t,TPP_Total} = the full price of product *d*, purchased at time period *t*, for TPP class purchasers.

P_{d,t,TPP_Copay} = the copay/coinsurance price of product *d*, purchased at time period *t*, for TPP class purchasers.

62. As seen in formulas (2) and (3) above, consumer copayment/coinsurance amounts are included in the Consumer Class and netted out of the End-Payor Class.

C. Methodology for the calculation of unjust enrichment damages

63. Retailers profited from the sale of the at-issue Valsartan products to consumers at the point of sale. Profits are defined as revenues minus costs for each at-issue Valsartan product sold by the Defendant Retailers from January 1, 2012 until the at-issue Valsartan products were recalled in 2018 and 2019 for being adulterated and misbranded.[63]

64. A simple equation representing the profits Defendant Retailers generated from selling the at-issue Valsartan products to consumers is presented in formula (4):

$$\text{Retailer Profits}_{d,t} = Revenue_{d,t} - Costs_{d,t} \quad (4)$$

Where:

$Revenue_{d,t}$ = the retailer revenue of product *d*, sold to consumers over time period *t*.

$Costs_{d,t}$ = the retailer costs of dispensing product *d* to consumers over time period *t*.

Retailer revenue can be expressed in formulas (5) as:

$$Revenue_{d,t} = Q_{d,t} * Consumer\_PPU_{d,t} \quad (5)$$

Where:

$Q_{d,t}$ = the quantity of units of product *d* sold to consumers over time period *t*.

$Consumer\_PPU_{d,t}$ = the average out of pocket cost per unit to consumers, of product *d* sold by the retailer, over time period *t*. This average out of pocket cost includes all payments incurred by the consumers including copayments and coinsurance.

[63] See footnote 3 above.

Retailer costs of dispensing to consumers can be expressed in formulas (6) as:

$$Costs_{d,t} = Q_{d,t} * Retailer\_CPU_{d,t} \quad (6)$$

Where:

$Q_{d,t}$ = the quantity of units of product *d* sold to consumers over time period *t*.

$Retailer\_CPU_{d,t}$ = the average retailer cost per unit of product *d*, over time period *t* to dispense to consumers.

65. The profits Defendant Retailers make off the sale of the at-issue Valsartan products are a function of the reimbursements they received from consumers when they sell the at-issue Valsartan products, aggregated over all at-issue Valsartan products sold by the Defendant Retailers to consumers in a given time period minus the costs to Defendant Retailers for dispensing the at issue products.[64]

66. Formals (5) and (6) can be used to expand formula (4) above as:

$$\text{Retailer Profits}_{d,t} = (Q_{d,t} * Consumer\_PPU_{d,t}) - (Q_{d,t} * Retailer\_CPU_{d,t}) \quad (7)$$

This formula can be rewritten as:

$$\text{Retailer Profits}_{d,t} = Q_{d,t} * (Consumer\_PPU_{d,t} - Retailer\_CPU_{d,t}) \quad (8)$$

67. Based on this, I can calculate unjust enrichment damages for each Defendant Retailer and aggregate across all Defendant Retailers and at-issue Valsartan products using data on revenues and costs relevant to the Defendant Retailers. To perform this calculation in practice, I rely on the Defendant Retailers data described below.

D. The At-Issue Valsartan Products

68. I have been instructed by Plaintiffs' Counsel to calculate theory of liability and unjust enrichment damages on all purchases of Valsartan products manufactured by the six Defendant Manufacturers. My calculations include all sales of at-issue Valsartan products to class members

[64] When calculating profits, other offsets may be removed from gross profits should the jury or Court find these to be reasonable deductions. These additional costs can easily be included in the Retailer_CPU input in formula (6) above.

from January 1, 2012 until the at-issue Valsartan products were recalled in 2018 and 2019[65] for being adulterated and misbranded.

69. Plaintiffs' Counsel have also provided me with a list of FDA-recalled NDC products to identify products that were manufactured by the Defendant Manufacturers but relabeled or repackaged under a different manufacturer name.[66] For all of the calculations described below, claims for repackaged NDCs have been included with those of their original Defendant Manufacturer.

70. When calculating damages for the Manufacturer theories of liability, Plaintiffs' Counsel have asked me to group the six Defendant Manufacturers into four groups, which are:

- ZHP and Torrent for all at-issue Valsartan claims, and Teva for at-issue generic Diovan (Valsartan and Valsartan-HCTZ) claims,
- Mylan for all at-issue Valsartan claims and Teva claims for at-issue generic Exforge (Amlodipine Valsartan and Amlodipine Valsartan-HCTZ) claims,
- Aurobindo for all at-issue Valsartan claims, and
- Hetero for all at-issue Valsartan claims.[67]

These four groupings are used in Attachments C through F and in Table 1 below.

E. Defendant Manufacturer Damages

71. [redacted]

[65] See footnote 3 above. Because Aurobindo's recall occurred on March 1, 2019, I exclude March 2019 from my damage calculations for at-issue Valsartan products manufactured by Aurobindo. For the other Defendant Manufacturers, I have been instructed by Plaintiffs' Counsel to include sales in the recall month in my calculations.

[66] "Search List of Recalled Angiotensin II Receptor Blockers (ARBs) including Valsartan, Losartan and Irbesartan FDA.xlsx." Note that a few Valsartan product NDCs in the FDA list were unclear about who the original manufacturer was. Three of these NDCs, which appear in the IQVIA data (54569648001, 54569658200, and 54569658300), were listed as being manufactured by either Teva or Solco (a subsidiary of ZHP). I used NDCs ASM000001-ASM000831 at 758, 774, and 791-793 to identify the correct manufacturer for these three Valsartan product NDCs.

[67] All damages for Hetero manufactured at-issue Valsartan products are limited to prescriptions sold in and after May 2018.

[redacted]

[70] See "Valsartan TPP Class Definitions and Exclusions".

[redacted]

G. Summary of Damages

79. The following tables present aggregate damages across all theories of liability. Details on aggregate damages for Defendant Manufacturer and Retailers at the group, subgroup, and state level are provided in Attachments C through I of this declaration. In Table 1, I present deduplicated, aggregate damages across all theories of liability for the Defendant Manufacturers.

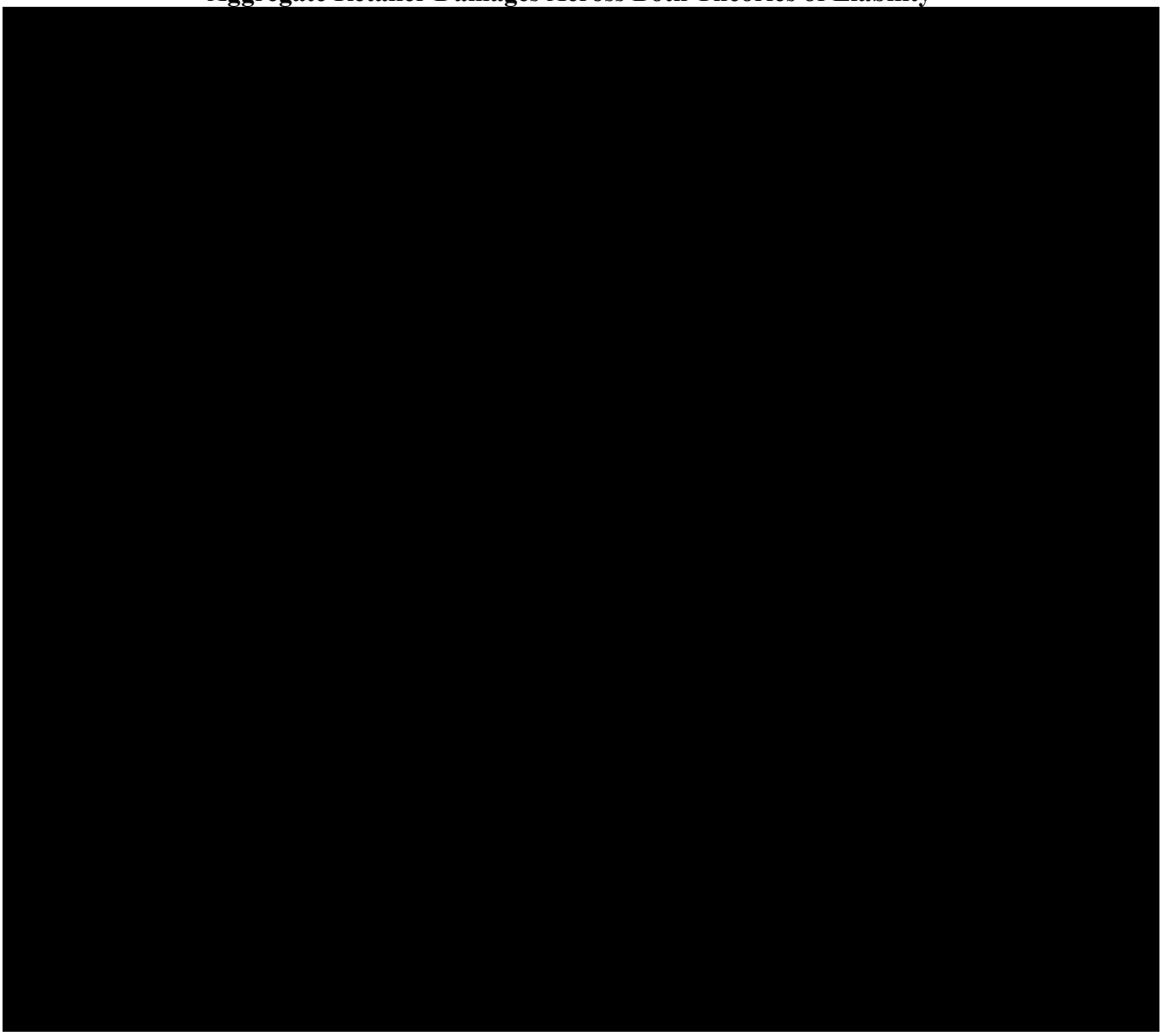
[71] See Section V.C above.

In Table 2, I present deduplicated, aggregate damages across all theories of liability for the Defendant Retailers. In Table 3, I present deduplicated, aggregate unjust enrichment damages for the Defendant Retailers. As described in footnote 62 above, some claims fall into multiple theories of liability. Therefore, total damages across Defendant Manufacturers, and Retailers are not intended to be summed.

Table 1
Aggregate Manufacturer Group Damages Across All Theories of Liability[72]

[72] Note that damages associated with claims that fall into multiple theories of Defendant Manufacturer liability have been deduplicated (i.e., only counted once) for this table.

Table 2
Aggregate Retailer Damages Across Both Theories of Liability[73]



VI. DEFENDANT WHOLESALER UNJUST ENRICHMENT DAMAGES

80. I have also been asked by Plaintiffs' Counsel to develop a methodology for calculating Defendant Wholesaler unjust enrichment damages for the at-issue Valsartan products. Like the

[73] Note that damages associated with claims that fall into multiple theories of Defendant Retailer liability have been deduplicated (i.e., only counted once) for this table.

Defendant Retailers, these companies profited from the distribution of the at-Issue Valsartan products to pharmacies and other entities. However, Defendant Wholesalers did not manufacture the at-issue Valsartan products, nor did they directly sell the product to consumers and TPPs. Consequently, the data that could be used to calculate unjust enrichment damages for Defendant Wholesalers differs from that of the Defendant Retailers described above.

81. Profits are defined as revenues minus cost for each at-issue Valsartan product distributed by the Defendant Wholesalers from January 1, 2012 until the at-issue Valsartan products were recalled in 2018 and 2019 for being adulterated and misbranded.[74]

82. A simple equation representing the profits wholesaler distributors generated from distributing the at-issue Valsartan products is presented in formula (9):

$$\text{Wholesaler Profits}_{d,t} = Revenue_{d,t} - Costs_{d,t} \quad (9)$$

Where:

$Revenue_{d,t}$ = the wholesaler revenue of product *d*, distributed over time period *t*.

$Costs_{d,t}$ = the wholesaler costs of goods sold of product *d*, distributed over time period *t*.

Wholesaler revenue can be expressed in formulas (10) as:

$$Revenue_{d,t} = Q_{d,t} * PPU_{d,t} \quad (10)$$

Where:

$Q_{d,t}$ = the quantity of units of product *d*, distributed by the wholesaler over time period *t*.

$PPU_{d,t}$ = the average price per unit of product *d*, distributed by the wholesaler over time period *t*.

Wholesaler costs can be expressed in formulas (11) as:

$$Costs_{d,t} = Q_{d,t} * CPU_{d,t} \quad (11)$$

[74] See footnote 3 above.

Where:

$Q_{d,t}$ = the quantity of units of product *d*, distributed by the wholesaler over time period *t*.

$CPU_{d,t}$ = the average cost per unit of product *d*, distributed by the wholesaler over time period *t*.

83. The profits Defendant Wholesalers make off the distribution of the at-issue Valsartan products are a function of both the costs the wholesalers are able to negotiate for the distribution of the products from the Defendant Manufacturer(s) and the reimbursements they received from pharmacies and other entities when they distributed the at-issue Valsartan products, aggregated over all at-issue Valsartan products acquired from the Defendant Manufacturers and distributed by the Defendant Wholesalers in a given time period.[75]

84. Formals (10) and (11) can be used to expand formula (9) above as:

$$\text{Wholesaler Profits}_{d,t} = (Q_{d,t} * PPU_{d,t}) - (Q_{d,t} * CPU_{d,t}) \quad (12)$$

This formula can be rewritten as:

$$\text{Wholesaler Profits}_{d,t} = Q_{d,t} * (PPU_{d,t} - CPU_{d,t}) \quad (13)$$

85. Based on this, I can calculate unjust enrichment damages for each Defendant Wholesaler and aggregated across all Defendant Wholesalers and at-issue Valsartan products using data on revenues and costs relevant to the Defendant Wholesalers.

86. To perform this calculation in practice, Plaintiffs' Counsel or the court would provide me with the appropriate input data, including data on quantities distributed, revenues, and costs associated with those quantities distributed of the at-issue Valsartan products by the Defendant Wholesalers.[76]

[75] When calculating profits, other offsets may be removed from gross profits should the jury or Court find these to be reasonable deductions. These additional costs can easily be included in the CPU input in formula (11) above.

[76] [redacted]

Rena Conti

Rena Conti

November 10, 2021

ATTACHMENT A

Curriculum vitae of Rena M. Conti, Ph.D.

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A.1. Academic appointments

- The University of Chicago
  - Instructor, Department of Pediatrics, Section of Pediatric Hematology and Oncology, 2006–2010.
  - Assistant Professor, Department of Pediatrics. Section of Pediatric Hematology and Oncology, 2010–2016.
  - Assistant Professor, Department of Public Health Sciences, 2013–2016.
  - Assistant Professor, Biological Sciences Collegiate Division, 2014–2016.
  - Associate Professor, Department of Pediatrics, Section of Pediatric Hematology and Oncology and Biological Sciences Collegiate Division, July 2016–July 2018.
  - Associate Professor, Harris School of Public Policy, January 2017–June 2018.
- Boston University
  - Associate Professor, Markets, Public Policy, and Law, Questrom School of Business, July 2018–present.
  - Associate Research Director, Biopharma and Public Policy, Institute for Health System Innovation and Policy, July 2018–present.

A.2. Education

- Kenyon College, BA, Philosophy (high honors)
- Harvard University, PhD, Interfaculty Initiative in Health Policy; Concentration: Economics, Dissertation title: ‘The Economic Value of Antidepressant Prescription Drugs’

A.3. Previous employment

- Research Manager, Harvard School of Public Health, 1998-2000
- Research Assistant, Department of Health Care Policy, Harvard Medical School, 2000-2006

A.4. Invited, elected, or appointed extramural service

- NCORP, Alliance/Cancer and Leukemia Group B, Committee on Cancer Control and Health Outcomes, 2006–present.
- Ad hoc advisor, Finance Committee, HELP Committee of the US Senate, 2011–present. Consulted on prescription drug market and Coronavirus matters.
- Ad hoc advisor, US House of Representatives, 2011–present. Consulted on prescription drug market and Coronavirus matters.
- Clinical Trial Design Task Force, Investigation Drug Steering Committee, VOI Working Group, Co-chair, National Institutes of Health (NIH)/National Cancer Institute (NCI), 2012–2014.
- Government Relations Committee, American Society for Clinical Oncology, 2013–2016.
- Advisor (ad hoc), 60 Minutes, CBS News, 2014.
- Chair, Pre-conference on the Economics of Cancer Treatment, American Society for Clinical Oncology, 2014–June 2018.
- Advisor (ad hoc), Public Interest Division, Illinois Attorney General, 2014-present.
- Consultant (permanent), Center for Health Policy and Outcomes, Department of Epidemiology & Biostatistics, Memorial Sloan-Kettering Cancer Center, 2014–2018.
- Member (elected), PDQ Board on Financial Toxicity, NIH/NCI, 2015–present.
- Member (elected), Conference on Research in Income and Wealth, 2016–present.
- Advisory board member (appointed), Midwest CEPAC, Institute for Clinical and Economic Review, 2016–present.
- Ad hoc advisor, Department of Public Health, State of Louisiana, 2016–present. Consulted on prescription drug market and Coronavirus matters.

- Ad hoc advisor, National Governors Association, 2016–present. Consulted on prescription drug and Coronavirus matters.
- Advisory committee member (appointed), State Alternative Approaches to Financing for Effective Drug Reimbursement & Utilization Group (SMART-D Initiative), 2016–present.
- Advisory panel member (appointed), Health Affairs Blog, Prescription drugs, 2016–present.
- Member (elected, ad hoc), National Academy of Sciences, Engineering, and Medicine Committee "Ensuring Patient Access to Affordable Drug Therapies," 2016–2018.
- Special advisor, US Food and Drug Administration, Office of Generic Drugs, CDER, 2018-present. Consulted on prescription drug market and Coronavirus matters
- Pharmaceutical Policy Subcommittee Lead, Pete Buttigieg, Democratic Presidential Candidate, 2019-2020. Consulted on prescription drug market and Coronavirus matters.
- Health Policy Committee Leadership Team, Pete Buttigieg, Democratic Presidential Candidate, 2019-2020. Consulted on prescription drug market and Coronavirus matters.
- COVID-19 Public Health Response Team Member, Pete Buttigieg, Democratic Presidential Candidate, 2020. Dedicated to prescription drug market and Coronavirus matters.
- Health Policy Committee Leadership Team, Joe Biden, Democratic Presidential Candidate, 2019-2020. Consulted on prescription drug market and Coronavirus matters.
- Manuscript reviewer for *American Economics Review, American Journal of Health Economics, American Journal of Public Health, British Medical Journal, Cancer, Journal of the American Medical Association, Journal of Clinical Oncology, Journal of General Internal Medicine, Journal of Health Economics, Journal of Mental Health Economics and Policy, Journal of the National Cancer Institute, Journal of Political Economy, Health Affairs, Health Economics, Health Services Research, Lancet, Medical Care, Nature, New England Journal of Medicine, Science*.

A.5. Testimony

A.5.a. Government testimony

- "An Economic Assessment of the Causes and Policy Implications of Current Specialty Drug Shortages," Senate Finance Committee, Drug Shortages: What Causes Them and What Can We Do about Them? Washington, DC, December. 2011.
- "An Economic Assessment of the Potential Paradoxical Effects of the 340B Program on the Financing and Organization of Medical Care," Invited written statement, US House of Representatives, Energy and Commerce Committee hearing on "Examining the 340B Drug Pricing Program," March 2015.
- "Who Makes This Drug? The Public Costs of Keeping the Identity of Contract Manufacturers of Biopharmaceuticals Secret," Public Hearing and Federal Register submission on the Reauthorization of the Prescription Drug User Fee Act, US Food and Drug Administration, White Oak, MD, July 2015.
- "Determinants of Generic Drug Supply and Price," Generic Drug User Fee Amendments of 2012 (GDUFA) Reauthorization, FY 2016 Regulatory Science Initiatives Part 15 Public Meeting, Public Hearing on the Reauthorization of the Prescription Drug User Fee Act, US Food and Drug Administration, White Oak, MD, May 2016.
- "High Prescription Drug Prices: Causes, Consequences, Reform Opportunities," Oral testimony and written prepared statement in front of the City of Chicago, Committee on Finance, Public hearing on "Chicago Drug Pricing Transparency Ordinance." August 2017.
- "Challenges in Maintaining Competition in Small Generic Drug Markets II," FDA Public Meeting, Ensuring Competition in Generic Drug Markets, Silver Spring, MD, October 2017.
- "High Prescription Drug Prices: Balancing Access and Affordability," Federal Trade Commission workshop on "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics," Washington, DC, November 2017.

A.5.b. Other testimony (last 5 years)

- March 2021: *In Re Novartis and Par Antitrust Litigation*, United States District Court for the Southern District of New York, Case No. 1:18-cv-04361-AKH (written report).
- November 2020: *In re Washtenaw County Employees Retirement System v. Walgreen Co., Gregory D. Wasson, and Wade Miquelon*, State of Illinois Northern District Court, No. 1:15-cv-03187-SJC-MMR (written report).
- November 2020, March 2021: *In re Ranbaxy Generic Drug Application Antitrust Litigation,* United States District Court for the District of Massachusetts, MDL No. 1:19-md-02878-NMG (written report, deposition).
- September 2020: *In re Glumetza Antitrust Litigation*, Humana Action (3:20-cv-05251-WHA), United States District Court for the Northern District of California, 3:19-cv-05822-WHA (written report).
- April 2019, May 2019: *Sheet Metal Workers Local No. 20 Welfare, et al. v. CVS Pharmacy*, Case No. 1:16-cv-00447-S, United States District Court for the District of Rhode Island (written reports, deposition).
- November 2018, January 2019: *In re Suboxone Antitrust Litigation*, MDL No. 2445, United States District Court for the Eastern District of Pennsylvania (written reports, deposition)
- June, August and September 2018: *Blue Cross Blue Shield Association, et al. v. GlaxoSmithKline LLC*, Civil Action No. 13-cv-04663-JS, United States District Court for the Eastern District of Pennsylvania (written reports, deposition).
- July and September 2017: *In re Asacol Antitrust Litigation*, United States District Court for the District of Massachusetts, Civil Action No. 1:15-cv-12730 (DJC) (written report, deposition).

A.6. Publications

A.6.a. Peer-reviewed publications in the primary literature, exclusive of abstracts

- Epstein, AM, JZ Ayanian, JH Keogh, SJ Noonan, N Armistead, PD Cleary, JS Weissman, JA David-Kasdan, D Carlson, J Fuller, D Marsh, and RM Conti. “Racial Disparities in Access to Renal Transplantation—Clinically Appropriate or Due to

Underuse or Overuse?" *New England Journal of Medicine*. 343, no. 21 (2000): 1537–44.

- Frank, RG, RM Conti, and HH Goldman. "Mental Health Policy and Psychotropic Drugs." *Milbank Quarterly*. 83, no. 2 (2005): 271–98.
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- Chien, AT, RM Conti, and HA Pollack. "A Pediatric-Focused Review of the Performance Incentive Literature." *Current Opinion in Pediatrics*. 19, no. 6 (2007): 719–25.
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- Meltzer, DO, A Basu, and RM Conti. "The Economics of Comparative Effectiveness Studies: Societal and Private Perspectives and Their Implications for Prioritizing Public Investments in Comparative Effectiveness Research." *Pharmacoeconomics.* 28, no. 10 (2010): 843–53.
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- Conti, RM, and PB Bach. "The 340B Drug Discount Program: Hospitals Generate Profits by Expanding to Reach More Affluent Communities." *Health Affairs (Millwood).* 33, no. 10 (2014): 1786–92.
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  - WSJ: Louisiana's Deal for Hepatitis C Drugs May Serve as Model
    - Also appears in Dow Jones Institutional News (according to Factiva)
  - Brookings: Louisiana's innovative drug purchasing program, and what it could mean for the country
  - Salon: Here's why the bipartisan push to lower drug prices never works
    - Appears on both national level and WBUR
  - Politico: Prescription Pulse: Trump drug pricing agenda dramatically shrinks
  - Medical Daily: Louisiana's Subscription Model For Hep C Drugs: What You Need To Know
    - Digest of NPR article
  - NPR: Louisiana's Novel 'Subscription' Model For Pricey Hepatitis C Drugs Gains Approval
    - Appears on both national level and 89.9 of NOLA (and other stations, saw WAMU 88.5 too, and I anticipate others ran the story)
  - Science Daily: Reforming pharmacy benefit manager practices may lead to drug cost savings
  - Wash Post: Low prices of some lifesaving drugs make them impossible to get

- Cost of Health Care News: Issue No. 46: Where the Cost Savings Are: Hospitals
- Cited in: House Energy and Commerce Subcommittee on Health Hearing; "Improving Drug Pricing Transparency and Lowering Prices for American Consumers."; Testimony by Frederick Isasi, Executive Director, Families USA; WAX52052119H006
- U Mich Institute for Healthcare Policy & Innovation: Opioid doctor and pharmacy "shoppers" may also shop at home, study suggests
- WBUR: $2 Million Drug? Treatment For Rare Genetic Disease Is Expected To Break Price Record
- AARP Español: Un plan de cinco puntos para reducir los precios de los medicamentos recetados
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A.7. Honors, prizes, and awards

- US Bureau of Labor Statistics, Price Index Research Division, Predoctoral Fellowship, Washington, DC, 2003–2004.
- National Institutes of Mental Health, Ruth L. Kirschstein Individual Predoctoral Fellowship, Cambridge, MA, 2004–2005.
- Alan Williams Fellowship in Health Economics, University of York, UK, 2007.
- Questrom School of Business, Angiola M. Noe Faculty Research Fund, 2019.
- Questrom School of Business, Dean's Research Scholar, 2019.

A.8. Invited speaking

A.8.a. Extramural: Peer-review selected

- Previous to 2017
  - "The Effect of FDA Advisories on Branded Pharmaceutical Firms."
    - Pharmaceutical Economics and Policy Conference, Miami, FL, May 2011.
    - International Health Economics Association, Annual Meeting, Toronto, CA, July 2011.
    - American Health Economics Association Annual Meeting, Minneapolis, MN, July 2012.
  - "The Discovery, Financing and Evaluation of Genomic Medicine: Implications for Cancer Care," Annual Society for Medical Decision Making, Organized Saturday Symposium, Toronto, Canada, October 2011.
  - "Anatomy of US Cancer Drug Shortages."
    - Global Health Economics Forum, Amsterdam, NE, June 2012.
    - National Bureau of Economic Research, Industrial Organization Seminar, Cambridge, MA, February 2013.

- Petrie Flom Center, Harvard Law School, Law and Economics Conference on the FDA, Cambridge, MA, May 2013.
- Industry Studies Conference, Supply Chain Response: Dealing with Disruption, Shortages, and Uncertainty, Kansas City, MO, June 2013.
- Massachusetts Institute of Technology, Sloan School of Business, micro@sloan Conference, Cambridge, MA, August 2013.

- "Are New Drugs More Expensive than Old Ones? Trends in the Benefit-Adjusted Launch Prices of Anticancer Drugs, 1995–2013," 2014 American Society of Clinical Oncology Annual Meeting, May 2014; Abstract published in *Journal of Clinical Oncology* 2014:32:5s (suppl; abstr 6525).
- "The Intended and Unintended Consequences of 340B Program Expansions," Bates White Life Sciences Symposium, Washington, DC, June 2014.
- "Specialty Drug Prices and Utilization after Loss of US Patent Exclusivity, 2001–2007."
  - American Society of Health Care Economists, LA, CA. June 2014.
  - International Health Economics Association, Annual Meeting, Podium presentation, Economics of Pharmaceuticals, Milan, Italy, July 2015.
- "The Economic Causes and Consequences of US Drug Shortages" (with ER Berndt), American Society of Health Care Economists, LA, CA, June 2014. Program available: https://ashecon.confex.com/ashecon/2014/webprogram/Session1339.html.
- "Who Makes This Drug? Challenges in Assessing Biopharmaceutical Industry Structure and Conduct," Society for Economic Measurement Annual Meeting, Chicago, IL, August 2014.
- "Estimating the Cost-Effectiveness of Tyrosine Kinase Inhibitor Treatment Strategies for Newly Diagnosed Chronic Myeloid Leukemia in Chronic Phase Following Imatinib's Generic Entry in the US."
  - 16th Annual John Goldman Conference, Philadelphia, PA, September 2014.
  - American Society of Hematologists Annual Meeting, San Francisco, CA, December 2014.

- International Health Economics Association, Annual Meeting, Podium Presentation, Economics of Cancer, Milan, Italy, July 2015.

- "The ACA's Effect on Outpatient Medical Practice Consolidation: Likely Price and Quality Outcomes," ACA Policy Diffusion Project, Robert Wood Johnson Foundation Conference: Diffusion of ACA Policies across the American states: What? How? Why? Chicago, IL, June 2015.
- "A Tale of Two (Drug) Prices."
  - Society for Economic Measurement Annual Meeting, Paris, France, July 2015.
  - Ashecon, J Philadelphia, PA, June 2016.
- "The Impact of Provider Consolidation on Outpatient Cancer Care Prices."
  - National Academy for State Health Policy Annual Conference, Dallas, TX, October 2015.
  - Healthcare Markets Conference, Kellogg School of Management, Northwestern University, Evanston, IL, April 2016.
  - Ashecon, Philadelphia, PA, June 2016.
- "Provider Consolidation and Outpatient Cancer Care Prices," National Academy for State Health Policy Webinar, December 2015.
  - "Patient Medication Adherence among HIV/AIDS Patients Receiving 340B-Purchased Antiretroviral Medications," International Society for Pharmacoeconomics and Outcomes Research, Washington, DC, May 2016.
- "Drug Prices: Follow the Money—How Costs and Payments Impact Diabetes Care," American Diabetes Association, Annual Meeting, Scientific Sessions, New Orleans, LA, June 2016.
- "The Economics of Drug Shortages," Organized Session, Ashecon, Philadelphia, PA, June 2016.
- "Medication Adherence among 340B Patients with Hypertension, Hyperlipidemia, and Diabetes," Academy Health Annual Meeting, Boston, MA, June 2016.

- "Generic Drug Prices Rise Worldwide, Why?" Society for Economic Measurement annual meeting, Thessolonki, Greece, July 2016.

- 2017
  - "GDUFA Reauthorization: Economic Perspective," Bates White Life Sciences Symposium, Washington, DC, May 2017.
  - "Hot Spots and Bad Actors: Prescription Drug Price Trends 2012–2014."
    - IMS Health Institute Research Forum, Boston, MA, May 2017.
    - Academy Health Annual Meeting, New Orleans, LA, June 2017.
- 2018
  - "Prices of and Spending on Outpatient Prescription Drug-Based Cancer Care after Physician Consolidation with Health Systems," Allied Social Sciences Association, Philadelphia, PA, January 2018.
  - "The Landscape of US Generic Prescription Drug Markets, 2004–2016," Organized Session, Ashecon, Atlanta, GA, June 2018.
- 2019
  - Facts Concerning Competition in Generic Drug Markets, Ashecon, Washington, DC, June 2019
  - The Incidence of Hospital Drug Price Subsidies: 340B, Drug Utilization, and Subsidized Medical Care, Ashecon, Washington, DC, June 2019
  - How Competitive Are U.S. Generic Prescription Drug Markets 2009-2016? Society for Economic Measurement annual meeting, Germany, August 2019
  - The Changing Geography of Prescription Pharmaceutical Supply: Levels, Trends and Implications, Society for Economic Measurement annual meeting, Germany, August 2019
  - Panelist, Improving Value in Healthcare, APPAM, Denver, Colorado, November 2019
  - Discussant, Policy Determinants of Prescription Drug Use, APPAM, Denver, Colorado, November 2019

- How Competitive Are U.S. Generic Prescription Drug Markets 2009-2016?, Emerging Evidence to Inform Medicare Prescription Drug Policy, APPAM, Denver, Colorado, November 2019

A.8.b. Extramural: Invited

- Previous to 2017
  - "The Effect of FDA Advisories on Branded Pharmaceutical Firms."
    - United States Food and Drug Administration, Washington, DC, May 2011.
    - DePaul University, Economics Department, Chicago, IL, October 2011.
  - "The Economics of Comparative Effectiveness Studies: Societal and Private Perspectives and Their Implications for Prioritizing Public Investments in Comparative Effectiveness Research," Decide Network Health Economics Seminar, Chicago, IL, May 2011.
  - "Antidepressant Treatment and Suicide Attempts in Children and Adolescents," Columbia University, School of Public Health, Department of Health Policy and Management, New York, June 2011.
  - "Infused Chemotherapy Use Following Patent Expiration among Individuals Aged 65 and Older," Chicago Council of Science and Technology Symposium, Chicago, IL, November 2011.
  - "The Economic, Legal and Scientific Implications of Gene Patents," Chicago Council of Science and Technology Symposium, Chicago, IL, November 2011.
  - "Anatomy of US Cancer Drug Shortages."
    - Massachusetts Institute of Technology, Sloan School of Management, Cambridge, MA, May 2012.
    - Massachusetts Institute of Technology, Sloan School of Management, Cambridge, MA, April 2013.
    - United States Government Accountability Office, Washington, DC, June 2013.
    - United States Bureau of Economic Analysis, Washington, DC, November 2013.

- "Show Me the Money: Reimbursement in an ACA World," 2014 BIO International Convention, New York, February 2013. Webcast available: https://www.youtube.com/watch?v=j6Cezq22woI.
- "The Intended and Unintended Consequences of 340B Program Expansions."
  - 2013 Bio International Convention, Payer Reimbursement and Drug Shortages Sessions, Chicago, IL, April 2013.
  - Institute of Medicine, National Cancer Policy Forum Workshop. Ensuring Patient Access to Cancer Drugs, Washington, DC, June 2014. Webcast available: https://www.iom.edu/Activities/Disease/NCPF/2014-JUN-09.aspx.
- "Economic Issues Underlying Recent Drug Shortages in the US," 2013 Bio International Convention, Payer Reimbursement and Drug Shortages Sessions, Chicago, IL, April 2013.
- "The Financing and Organization of Rare Disease Pharmacotherapy," Genzyme, Global Health Policy Symposium, Approaches to Value and Modeling in Rare Diseases, Cambridge, MA, May 2013.
- "Trends and Determinants of Novel Anti-Cancer Drug Launch Prices in the United States," University of North Carolina Chapel Hill, Health Policy and Management, Chapel Hill, NC, December 2013.
- "Specialty Drug Prices and Utilization after Loss of US Patent Exclusivity, 2001–2007."
  - Pfizer Health Economics Seminar, New York, May 2014.
  - Health Economics Workshop, Emory University Rollins School of Public Health, Atlanta, Georgia, May 2015.
- "Bending the Cost Curve in Cancer Treatment: The ACA and Beyond."
  - ASCO Annual Meeting, Chicago, IL, May 2014.
  - Best of ASCO Annual Meeting, Seattle, Washington, August 2014.
- "Pricing in the Market for Anticancer Drugs," NCI and Accenture Strategic Panel on Life Science Innovation. Chicago, IL, May 2014.
- "Specialty Drug Spending," Accenture Life Sciences Annual Meeting, Washington, DC, October 2014.

- "National Trends in Spending on and Use of Oral Oncologics, 2006–2011," Health Affairs Briefing: Specialty Pharmaceuticals, October 2014.
- "The 340B Drug Discount Program: Hospitals Generate Profits by Expanding to Reach More Affluent Communities," Health Affairs Briefing: Specialty Pharmaceuticals, October 2014.
- "Pricing in the Market for Anticancer Drugs."
  - MIT Sloan School of Business CANCER Rx Conference, Boston, MA, October 2014.
  - Health Economics Seminar, University of Iowa, Department of Economics, November 2014.
  - UCLA Seminar on Pharmaceutical Economics and Policy, Los Angeles, CA, December 2014.
  - University of Illinois Chicago, Pharmacy Systems, Outcomes and Policy lunchtime seminar, Chicago, IL. January 2015.
- "Access to and Value of Treatment Innovation in Blood Cancers," American Cancer Society CRP Cancer Care Delivery Research Committee, Chicago, IL, November 2014.
- "Ebola-Economics—The Cost of Health Crisis: Measuring the Economic and Human Toll of Pandemics," Illinois Humanities Council, Chicago, IL. January 2015. Webcast available: http://cantv.org/watch-now/the-cost-of-health-crisis-measuring-the-economic-and-human-toll-of-pandemics/.
- "Bending Medicare's Cost Curve in Cancer Care," Grand Rounds Invited Speaker, Winship Cancer Institute, of Emory University, Atlanta, Georgia, May 2015.
- "Health Economist's View of Value-Based Care," ASCO Annual Meeting, "Alternatives to ASP-Plus-Six: What Are the Options?" Chicago, IL, May 2015.
- "Changing the Incentives for Specialty Drug Development," Keynote Speaker, Sachs Immuno-Oncology: BD&L and Investment Forum, Chicago, IL, May 2015.

- "Criteria Needed to Be Implemented before Making Innovative Drug Pricing a Reality," NCI and Accenture Strategic Panel on Life Science Innovation. Chicago, IL, May 2015.
- "Pricing for Value: Specialty Drugs: Paying for Value: Policy Options for Managing the Cost of PCSK9 Inhibitors and Other Specialty Drugs," Pew Charitable Trusts, Washington, DC, October 2015.
- "Generic Drug Prices Rise, Why?" US Senate Health Education Labor and Pensions Subcommittee, health policy staff conference, Washington, DC, January 2016.
- "Cancer Drugs: The Economics of Access and Affordability."
  - The Leukemia & Lymphoma Society, Thought Leadership Roundtable, "Blood Cancers: Standards of Care, Gateways to Cancer Cures," Invited panelist, February 2016.
  - University School of Medicine, Department of Health Policy, "Special Lecture Series on Value in Oncology Care," Invited panelist, March 2016.
- "The ACA's Effect on Oncology Practice Consolidation: The Prices of Outpatient Cancer Treatments," Invited talk for the Robert Wood Johnson Health Policy Scholars, University of Michigan, Ann Arbor, MI, April 2016.
- "The Impact of Provider Consolidation on Outpatient Cancer Care Prices," Johns Hopkins University School of Public Health, Baltimore, MD, April 2016.
- "The Economics of Specialty Drug Spending: Opportunities for Reform."
  - American Medical Association, Leadership Policy Committee, Chicago, IL, June 2016.
  - Invited workshop, Senator Bill Cassidy and Health Policy Staff, Washington, DC, July 2016.
  - Invited workshop, Senator Al Franken and Health Policy Staff, Washington, DC, July 2016.
  - Manhattan Institute, New York, November 2016.
- "Drug Prices: Value, Affordability, and Advocacy," Invited Panelist, Doctors for America Webinar June 2016.

- "The Economics of Specialty Drug Spending: Opportunities for Reform and Research," University of Colorado, Department of Medicine, Denver, CO, July 2016.

- "Prescription Drug Prices: The Promises and Perils of Alternative Payment Models," Leadership Consortium for a Value & Science-Driven Health System, National Academy of Medicine, September 2016.
- Discussion comments on "Pass-Through in a Highly Regulated Supply Chain," 27th Annual Health Economics Conference, Vanderbilt University, Nashville, TN, October 2016.
  - "Financing the Safety Net: Now and in the Future," University of Kansas Medical Center, Medical Care Executive Training Program, Kansas City, KS, November 2016.
- "The Prices of Outpatient Prescription Drug-Based Cancer Care after Physician Consolidation with Health Systems," University of Kansas Medical Center, Health Policy Research Group, presentation followed by panel discussion, Kansas City, KS, November 2016.
- "The Economics of Medical Practice Consolidation," Large Urology Group Practice Association Annual Meeting, Chicago, IL, November 2016.

- 2017
  - "Ensuring Access to HIV & Hepatitis C Treatment: Economic Challenges and Opportunities," President's Advisory Commission on HIV/AIDs, Washington, DC, March 2017.
  - "High Prescription Drug Prices: Causes, Consequences, Reform Opportunities."
    - Columbia University School of Public Health and Comprehensive Cancer Center, New York, April 2017.
    - Altarum Center for Sustainable Health Spending Presents: Beyond the ACA: Health Policy and Sustainable Health Spending, Washington, DC, July 2017.
  - "High Prescription Drug Prices: What Should Employers Do to Curb Spending?" National Business Group on Health Roundtable Discussion, Washington, DC, April 2017.

- "Price Estimates for HCV Prescription Drug-Based Treatments under 1498," Hepatitis C Treatment and Section 1498 Meeting, Webcast. Johns Hopkins University School of Public Health, Baltimore, MD, April 2017.
- "Consumer Learning and the Entry of Generic Pharmaceuticals," Discussant, Midwest Health Economics Conference, Minneapolis, MN, May 2017.
- "Cancer Economics in the Trump Years," ASCO Annual Meeting, Chicago, IL, June 2017.
- "Prescription Drug Reimbursement Opportunities and Challenges in 2017–2018," Sachs Associates: Immuno-oncology Investor Forum, Chicago, IL, June 2017.

"Value Assessments Are a Necessary, Not Sufficient Condition to Ensure Access to New Prescription Drugs," Health Affairs/Project Hope Policy Forum: Understanding the Value of Innovations in Medicine, Washington, DC, September 2017.

- "High Prescription Drug Prices: Balancing Access and Affordability," Washington State Medical Oncology Society, Seattle, WA, October 2017.

- 2018
  - Tuesday Plenary: Economics and the Drug Pricing Debate, Ashecon, Atlanta, GA, June 2018.
  - Medical Product Shortages during Disasters: Opportunities to Predict, Prevent, and Respond: A Workshop, National Academy of Medicine, September 2018.
  - The Cost of a Cure: Creating Sustainable Solutions for Gene and Cell Therapies. Leonard Davis Institute, University of Pennsylvania, September 2018
- 2019
  - How Competitive Are U.S. Generic Prescription Drug Markets, 2009-2016, UCLA, Pharmaceutical Economics and Policy Seminar, April 2019
  - Panelist, Drug Pricing Reform, Alliance for Health Policy Senate Health Care Retreat, Virginia, April 2019
  - How Competitive Are U.S. Generic Prescription Drug Markets, 2009-2016, BU Law School, May 2019

- Where are we going on Drug Pricing? Keynote, Tufts Center for Economic Value Research Annual Meeting, Boston June 2019
- Discussant, Safety Net Cutbacks and Hospital Service Provision: Evidence from Psychiatric Care, Ashecon, Washington, DC, June 2019
- Discussant, Effects of Pharmaceutical Patents on Patient Welfare: Evidence from Generic Entry of Oral Breast Cancer Therapies, Ashecon, Washington, DC, June 2019
- Monday Plenary: The Future of Drug Pricing, Ashecon, Washington, DC June 2019
- Altarum: Altarum's Ninth Annual Sustainable Health Care Spending Symposium, June 2019
- The Hill: Future of Healthcare Summit, Washington, DC, June 2019
- Pricing for innovative therapies, Analysis Group: Law & Economics Symposium, June 2019
- Panelist, Brookings Institute: Louisiana's prescription drug experiment: A model for the nation? July 2019
  - Brookings write-up: https://www.nifusa.org/panel-report-netflix-model-for-pharmaceuticals-at-brookings/
- Q1 Productions: 4th Annual Pharmaceutical Strategic Pricing Conference, Philadelphia September 2019
- Panelist, Defining and Assessing Drug Value Kaiser Permanente's Institute for Health Policy forum, *Unpacking Drug Value: A Path to Fair Pricing,* Washington, DC September 2019
- Panelist, Exploring the Value and Cost-Effectiveness of CAR T-cell Therapy, AACI, Washington, DC, October 2019
- Panelist, The Atlantic: Future of Healthcare Summit, Washington, DC, October 2019
- Pricing for innovative therapies. Innovative Genomics Institute and Center to Advance Science in Policy & Regulation Joint Seminar, University of California - Berkeley, October 2019

- Challenges to the domestic supply of generic drugs. Research Day, IQVIA Boston, October 2019
- The domestic supply of off-patent prescription drugs. Second Annual Intellectual Property & Innovation Conference, Suffolk Law School, Boston, October 2019

A.9. Intramural speaking

- University of Chicago
  - Previous to 2017
    - "How Do Initial Signals of Quality Influence the Diffusion of New Medical Products? The Case of New Cancer Treatments," The University of Chicago, Section of Hematology/Oncology, Research Seminar Series, April 2011.
    - "Infused Chemotherapy Use Following Patent Expiration among Individuals Aged 65 and Older," The University of Chicago, Health Economics Workshop, May 2011.
    - "The Effect of FDA Advisories on Branded Pharmaceutical Firms," The University of Chicago, Health Economics Workshop, October 2011.
    - "The Impact of FDA Regulatory Actions on Bevacizumab Use for Breast Cancer," The University of Chicago, Cancer Economics Lunchtime Seminar, April 2012.
    - "The Prevalence of On-Label Use of Patent Protected Anti-Cancer Drugs," The University of Chicago, Health Economics Workshop, April 2012.
    - "Anatomy of US Cancer Drug Shortages."
      - Cancer Economics Lunchtime Seminar, November 2012.
      - Cancer Economics Lunchtime Seminar, March 2013.
    - "Trends and Determinants of Novel Anti-Cancer Drug Launch Prices in the United States," The University of Chicago, Health Economics Workshop, April 2013.
    - "Bending the Cost Curve in Cancer Treatment: The ACA and Beyond," Health reform: Maclean Center Seminar Series, February 2014.
    - "Specialty Drug Prices and Utilization after Loss of US Patent Exclusivity, 2001–2007," Cancer Economics Lunchtime Seminar, March 2014.

- "Pricing in the Market for Anticancer Drugs," 2014 Symposium on Pharmaceutical Policy and Vulnerable Populations, September 2014.
- "Cures for High and Growing Spending on Pharmaceuticals," Grand Rounds, Pritzker School of Medicine, August 2015.
- "The Economics and Financing of Prescription Drug Supply Chains," Annual Healthcare Conference moderator, Booth School of Business, October 2015.
- "The Impact of Provider Consolidation on Outpatient Cancer Care Prices," Cancer Health Policy Seminar, December 2015.
- Panelist, "Government Regulation in Pharmaceutical Pricing: Too Much or Too Little?" Chicago Booth's 15th Annual Healthcare Conference, November 2016.
- Panelist, "What's Next for Obamacare? The Future of Insurance Coverage and Healthcare," Booth Health Care Group and the Graduate Program in Health Administration and Policy, December 2016.

2017

- Panelist, "What's Next for Obamacare? The Future of Insurance Coverage and Healthcare," Undergraduate Interest Group in Health Policy and the Graduate Program in Health Administration and Policy, April 2017.
- Debate moderator, "What's Next for Health Insurance?" Chicago Booth's 16th Annual Healthcare Conference, November 2017.
- Invited Respondent on "Moral Failure and Health Care Costs: How the Political System Gets Health Care Wrong," Jeffery Goldsmith, November 2017.

Questrom School of Business

2019

- "Moral hazard and the 340B drug discount program", Harvard-BU-MIT Health Economics Workshop, February 2019
- Discussion moderator, "Panel: The Rising Costs of Pharmaceuticals and Value Based Care", BU Health & Life Sciences Conference, November 2019

- IHSIP
  - 2019
    - "The Future of Drug Pricing", The National Defense University Visit March 2019
    - "The Future of Drug Pricing", The Inaugural IHSIP Health Policy Workshop, August 2019

A.10. Courses taught

A.10.a. The College (AB, BA, BS)

- Harvard University
  - EC 24: Health Economics, Teaching Fellow with David Cutler, Harvard College. 2 1.5-hour sections/week. Fall semester. 2002–2004.
- University of Chicago
  - BIOS 29294: Introduction to Global Health, Guest Lecturer (3 days, 1.5-hour sessions) investments in health, the financing and organization of vaccine development. S. Olopade & J. Schneider. Winter quarter. 2011, 2014, 2016.
  - PBHS 38010: Introduction to Health Economics, Course Co-director with R. Tamara Konetzka, 2 1.5-hour sections/week. Winter quarter. 2017, 2018.

A.10.b. Graduate programs (MBA, MS, MAPP, PhD)

- Harvard University
  - Teaching Fellow with Joseph Newhouse, Health Policy, Kennedy School of Government; 3 2-hour sessions/week. Spring semester. 2002.
- University of Chicago
  - CCTS 45200: Fundamentals of Health Services Research: Theory, Methods and Applications. 1–4 1.5-hour sessions/year on the Fundamentals of Health Economics, Health Reform and the Economics and Regulation of the Biopharmaceutical Industry. Summer quarter. 2007–2018.
  - PPHA 42610/CCTS 40002 Biomedical Tech: Innovation, Investment and Management, Course Director, 1 3-hour session/week. Spring quarter. 2009–2014, 2016.

- CABI 47500/CCTS 40001: Pharmacogenomics. The economics of genetic tests and treatments in Clinical Pharmacogenomics, 1 1.5-hour lecture. E. Dolan. Spring quarter. 2009–2018.
- HSTD 38400: Advanced Topics in Health Economics, Course Co-director with R. Tamara Konetzka, 2 1.5-hour sections/week. Fall quarter. 2011, 2015, 2016.
- PBHS 38010: Introduction to Health Economics. Course Co-director with R. Tamara Konetzka, 2 1.5-hour sections/week. Winter quarter. (Please note this course is also listed above). 2017, 2018.
- PPHA 42620: Biopharmaceutical Technology: Innovation, Investment & Strategy. Course director, 3 1-hour lectures/week. Spring quarter. 2018.

- Questrom School of Business
  - HM848 Driving Innovation in the Health Sector. Course director, 3 hour lectures/week. Spring semester. 2019
  - HM848 Driving Innovation in the Health Sector. Course director, 3 hour lectures/week. Spring semester. 2020
  - BA755 Describing, Analyzing, and Using Data. Course co-director, Daily lectures, three sections/week. September 2020.

A.10.c. Graduate medical education (residency and clinical fellowships)

- CCTS 45200: Fundamentals of Health Services Research: Theory, Methods and Applications. 1–4 1.5-hour sessions/year on the Fundamentals of Health Economics, Health Reform and the Economics and Regulation of the Biopharmaceutical Industry. Summer quarter. (Please note this course is also listed above). 2007.
- CTSA 1: The commercialization of biomedical technologies at academic research institutions, 1.5 hour/week, Course Director, Winter quarter. 2011.

A.11. Intramural service

A.11.a. Committee membership

- University of Chicago
  - University of Chicago, Biological Sciences Division, Institutional Review Committee, Committee C, 2007–2018.

- Questrom School of Business
  - Subcommittee of HSM PDC 2018-present
  - MS biopharma leadership and innovation development committee 2018-present

A.11.b. Center and program mentorship

- University of Chicago
  - Center for Health and the Social Sciences, 2006–2018.
  - The Graduate Program on Health Administration and Policy, 2008–2018.
  - Center for Translational and Policy Research of Chronic Diseases, 2013–2018.

A.11.c. Leadership

- University of Chicago
  - Co-organizer of Health Economics Workshop, Harris School of Public Policy, September 2006–2018.
  - Pediatrics Department, Director of Health Economics residents and fellows training program (joint with Harris School of Public Policy), January 2010–2016.
  - Co-organizer of Cancer Health Economics and Policy Workshop, University of Chicago Comprehensive Cancer Center, September 2010–2017.
  - Department of Public Health Sciences, PhD Admissions Committee, Ad hoc member, 2010–2017.
  - Biological Sciences Division, Diversity and Inclusion Plan Strategy Team leader, May 2013–2016.
  - Director of Public Policy and Health Economics residents and fellows training program, Pediatrics Department (joint with Harris School of Public Policy), June 2016–2017.

A.12. Grants

- Generic Cancer Drugs: Pricing and Affordability, Sponsored Program (IO) 9660304125, Sponsor Award Number RSGI-16-163-01-CPHPS, American Cancer Society, ends 12/31/2020, Award amount: 540,841.64
- Assessing Financial Difficulty in Patients with Blood Cancer, Sponsored Program (IO) 9660304125, Sponsor Award Number, Leukemia and Lymphoma Award, ends 12/31/2020, Award amount: $800,666

- Measuring the Impact and Size of Hospital 340B Revenues, Sponsored Program (IO) 9660304125, The Commonwealth Fund, ended 5/31/2019, Award amount: 80,655.70
- Towards a new paradigm for supporting drug pricing and innovation, Sponsored Program (IO) 95503033872, Laura and John Arnold Foundation, ends 12/31/2020, Award amount: 195,528.00

ATTACHMENT B

Attachment B: Materials Relied Upon

Bates Numbered Documents

ASM000001-831

Case Documents

Declaration of Humana Inc., *in this matter*, October 27, 2021.

Declaration of Matthew Sample, *in this matter*, June 16, 2020.

Third Amended Consolidated Economic Loss Class Action Complaint, In re: Valsartan, Losartan, and Irbesartan Products Liability Litigation, United States District Court for the District of New Jersey, No. 1:19-md-2875-RBK, Docket Entry No. 1708.

Valsartan Consumer Class Definitions and Exclusions, provided by counsel.

Valsartan TPP Class Definitions and Exclusions, provided by counsel.

Other Documents

21 C.F.R. § 314.94(9)(ii)

21 U.S.C. § 331(a)-(c)

21 U.S.C. § 351

Academy of Managed Care Pharmacy, "Pharmaceutical Payment Methods, 2013 Update," available at https://www.amcp.org/sites/default/files/2019-03/Full-Pharmaceutical-Guide-(3.0).pdf.

American Society of Health-System Pharmacists, "ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System," *American Journal of Health Systems Pharmacy*, 78(10), May 2021, pp. 907-918, available at https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/gdl-pharmacy-therapeutics-committee-formulary-system.ashx.

American Society of Health-System Pharmacists, "ASHP statement on the pharmacy and therapeutics committee and the formulary system," *American Journal of Health Systems Pharmacy*, 2008, pp. 213-215, available at https://www.ashp.org/-/media/assets/policy-guidelines/docs/statements/pharmacy-and-therapeutics-committee-and-formulary-system.ashx

Banuelos, H., "More Scrutiny for cGMP Violations, DOJ to pursue enforcement," *Contract Pharma,* May 6, 2013, available at https://www.contractpharma.com/issues/2013-05/view_fda-watch/more-scrutiny-for-cgmp-violations.

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Britt, R., "'Big Three' Pharma Distributors Post Sharp Gains," *MarketWatch*, September 15, 2010, available at https://www.marketwatch.com/story/big-3-pharma-distributors-post-sharp-gains-2010-09-15.

Conti, R.M., "Secretive Contract Manufacturing Arrangements Complicate Solutions to Shortages of Generics," *The Cancer Letter*, January 3, 2014, available at https://cdn.cancerhistoryproject.com/media/2014/01/10000000/TCL40-01.

Danzon, P.M., and E.L. Keuffel, "Regulation of the Pharmaceutical-Biotechnology Industry," *Economic Regulation and Its Reform: What Have We Learned?*, ed. N.L. Rose, University of Chicago Press: Chicago, IL, 2005, pp. 407-84.

Deloitte Consulting and the Healthcare Distribution Alliance, "The role of distributors in the US health care industry: 2019 report," 2019, available at https://www2.deloitte.com/content/dam/Deloitte/us/ Documents/life-sciences-health-care/us-hda-role-of-distributors-in-the-us-health-care-industry.pdf.

Ellis, L., "Snapshot of the American Pharmaceutical Industry," Harvard T.H. Chan School of Public Health, July 14, 2016, available at https://www.hsph.harvard.edu/ecpe/snapshot-of-the-american-pharmaceutical-industry/.

Food and Drug Administration (FDA), "About OCI," May 22, 2018, available at https://www.fda.gov/ICECI/CriminalInvestigations/ucm550316.htm.

FDA, "Criminal Investigations," May 30, 2018, available at https://www.fda.gov/ICECI/CriminalInvestigations/default.htm.

FDA, "Current Good Manufacturing Practice (CGMP) Regulations," available at https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations.

FDA, "Drug Supply Chain Security Act (DSCSA)," May 11, 2018, available at https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/.

FDA, "Facts About the Current Good Manufacturing Practices (CGMPs)," October 6, 2017, available at https://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm.

FDA, "FDA Updates and Press Announcements on Angiotensin II Receptor Blockers (ARB) Recalls (Valsartan, Losartan, and Irbesartan), available at https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan.

FDA, "Frequently Asked Questions about Drug Shortages: What can FDA do to address drug shortages?" updated November 13, 2020, available at https://www.fda.gov/drugs/drug-shortages/frequently-asked-questions-about-drug-shortages#q5.

FDA, "Investigative Priorities," June 21, 2017, available at https://www.fda.gov/ICECI/CriminalInvestigations/ucm546093.htm.

FDA, Orange Book Preface, available at https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface.

FDA, "Part I: The 1906 Food and Drugs Act and Its Enforcement," April 24, 2019, available at https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-i-1906-food-and-drugs-act-and-its-enforcement.

FDA, "Pharmaceutical Quality Resources," April 26, 2018, available at https://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/default.htm.

FDA, "Process Validation: General Principles and Practices," at pp. 3-4, available at https://www.fda.gov/files/drugs/published/Process-Validation--General-Principles-and-Practices.pdf.

FDA, "Promoting Safe & Effective Drugs for 100 Years," March 27, 2018, available at https://www.fda.gov/AboutFDA/History/ProductRegulation/ucm2017809.htm.

FDA, "Strategic Plan for Preventing and Mitigating Drug Shortages," October 2013, available at https://www.fda.gov/media/86907/download.

Food Drug Law Institute's Workshop, "Introduction to Drug Law and Regulation: Regulation of Drug Manufacturing," November 8-9, 2010, available at https://www.alston.com/-/media/files/insights/events/2010/11/introduction-to-drug-law-and-regulation-how-the-go/files/cirotta-and-burgess-11-9-10--regulation-of-drug-ma/fileattachment/cirotta-and-burgess-11-9-10--regulation-of-drug-ma.pdf.

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Healthcare Distribution Alliance, "Pharmaceutical Traceability," available at https://www.healthcaredistribution.org/issues/pharmaceutical-traceability.

Kaiser Family Foundation, "10 FAQs on Prescription Drug Importation," July 28, 2012, available at https://www.kff.org/medicare/issue-brief/10-faqs-on-prescription-drug-importation/.

McGinley, L., "Four former FDA commissioners denounce drug importation citing dangers to consumers," *Washington Post*, March 17, 2017, available at https://www.washingtonpost.com/news/to-your-health/wp/2017/03/17/four-former-fda-commissioners-denounce-drug-importation-citing-dangers-to-consumers/?noredirect=on&utm_term=.9bc5f9a6ffcd.

Morgan Lewis, "Medical Reimbursement for Drugs and Devices," Emerging Life Sciences Companies, second edition, Chapter 18, pp. 139-148, available at https://www.morganlewis.com/topics/entrepreneurresources/~/media/files/Special Topics/ERH_pubs/ERH_MedicareReimbursementForDrugsAndDevices_ELSCDeskbook.

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Pharmaceutical Research and Manufacturers of America, "The biopharmaceutical industry's commitment to quality," February 11, 2016, available at https://catalyst.phrma.org/the-biopharmaceutical-industrys-commitment-to-quality.

"Public Law 108-173, Medicare Prescription Drug, Improvement, and Modernization Act of 2003," December 8, 2003, available at https://www.congress.gov/108/plaws/publ173/PLAW-108publ173.pdf.

"Public Law 113-54, Drug Qualities and Securities Act," November 27, 2013, available at https://www.congress.gov/113/plaws/publ54/PLAW-113publ54.pdf.

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Shulkin, D., "Reinventing the Pharmacy and Therapeutics Committee," *Pharmacy and Therapeutics*, November 2012, 37(11), pp. 623-624, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3498992/.

Teva Form 10-K, 2017, available at https://www.sec.gov/Archives/edgar/data/818686/000119312518039076/d529462d10k.htm.

United States Department of Health and Human Services, "HHS Task Force on Drug Importation," December 2004, available at http://www.safemedicines.org/wp-content/uploads/2018/03/HHS-Report1220.pdf.

United States Department of Justice, "Deputy Assistant General Maame Ewusi-Mensah Frimpong Speaks at the 2013 CBI Pharmaceutical Compliance Congress," January 29, 2013, available at https://www.justice.gov/opa/speech/deputy-assistant-attorney-general-maame-ewusi-mensah-frimpong-speaks-2013-cbi.

United States Department of Justice, "GlaxoSmithKline to Plead Guilty & Pay $750 Million to Resolve Criminal and Civil Liability Regarding Manufacturing Deficiencies at Puerto Rico Plant," October 26, 2010, available at https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-pay-750-million-resolve-criminal-and-civil-liability-regarding.

Electronic Data

"Search List of Recalled Angiotensin II Receptor Blockers (ARBs) including Valsartan, Losartan and Irbesartan FDA.xlsx," provided by counsel.

IQVIA Xponent data:

CDS_ZXBK3_CLIENT_OUTPUT_COPAY_CSV

CDS_ZXBK4_CLIENT_OUTPUT_TPRICE_CSV

IQVIA Managed Care Workbook - November 2020.xlsx

IQVIA Plan Model Type Listing.xlsx

Retailer claims data:

Albertsons:

Albertsons Valsartan Summary 2012 - 2020 supplemental.xlsx

Albertsons Valsartan Summary 2012 - 2020.xlsx

CVS:

000000_CVS_MDL2875_0000000527.XLSX
000001_CVS_MDL2875_0000000515.XLSX
000002_CVS_MDL2875_0000000521.XLSX
000003_CVS_MDL2875_0000000514.XLSX
000004_CVS_MDL2875_0000000518.XLSX
000005_CVS_MDL2875_0000000507.XLSX
000006_CVS_MDL2875_0000000525.XLSX
000007_CVS_MDL2875_0000000524.XLSX
000008_CVS_MDL2875_0000000516.XLSX
000009_CVS_MDL2875_0000000522.XLSX
000010_CVS_MDL2875_0000000506.XLSX
000011_CVS_MDL2875_0000000513.XLSX
000012_CVS_MDL2875_0000000512.XLSX
000013_CVS_MDL2875_0000000523.XLSX
000014_CVS_MDL2875_0000000519.XLSX
000015_CVS_MDL2875_0000000511.XLSX
000016_CVS_MDL2875_0000000508.XLSX
000017_CVS_MDL2875_0000000517.XLSX
000018_CVS_MDL2875_0000000510.XLSX
000019_CVS_MDL2875_0000000526.XLSX
000020_CVS_MDL2875_0000000520.XLSX
000021_CVS_MDL2875_0000000509.XLSX
Task10936_ResultsA.xlsx
Task10936_ResultsB.xlsx
Task10936_ResultsC.xlsx
valsartan.xls

Express Scripts:

Express_Scripts_1120_00001066.csv
Express_Scripts_1120_00001067.csv

Express_Scripts_1120_00001068.csv
Express_Scripts_1120_00001069.csv
Express_Scripts_1120_00001070.csv
Express_Scripts_1120_00001071.csv
Express_Scripts_1120_00001072.csv
Express_Scripts_1120_00001073.csv
Express_Scripts_1120_00001074.csv
Express_Scripts_1120_00001075.csv
Express_Scripts_1120_00001076.csv

Kroger:

[KROG-000687 Restricted Confidential Information] Valsartan Sales - RFP 5.xlsx

Optum:

Valsartan_Dispensing_Data_2012_2016.xlsx
Valsartan_Dispensing_Data_2017.xlsx
Valsartan_Dispensing_Data_2018.xlsx

Rite-Aid:

Rite Aid Valsartan Sold Prescriptions RAD 2012 through 2014.xlsx
Rite Aid Valsartan Sold Prescriptions RAD 2015Q1 and 2015Q2.xlsx
Rite Aid Valsartan Sold Prescriptions RAD 2015Q3 and 2015Q4.xlsx
Valsartan Sold Prescriptions RAD 2016Q1 and 2016Q2.xlsx
Valsartan Sold Prescriptions RAD 2016Q3 and 2016Q4.xlsx
Rite Aid Valsartan Sold Prescriptions RAD 2017Q1 and 2017Q2 (1).xlsx
Rite Aid Valsartan Sold Prescriptions RAD 2017Q3 and 2017Q4.xlsx
Rite Aid Valsartan Sold Prescriptions RAD 2018Q1.xlsx
Rite Aid Valsartan Sold Prescriptions RAD 2018Q2 (1).xlsx
RIte Aid Valsartan Sold Prescriptions RAD 2018Q3.xlsx
Rite Aid Valsartan Sold Prescriptions RAD 2018Q4.xlsx

Walgreens:

000009_WALGREENS0001131.XLSX
000011_WALGREENS0001133.XLSX
000012_WALGREENS0001134.XLSX

000013_WALGREENS0001135.XLSX
000014_WALGREENS0001136.XLSX
000015_WALGREENS0001137.XLSX
000019_WALGREENS0001424.XLSX

Walmart:

sartan_1_final_11192020.csv
sartan_2_final_11192020.csv
sartan_3_final_11192020.csv
sartan_4_final_11192020.csv
sartan_5_final_11192020.csv
sartan_6_final_11192020.csv
sartan_7_final_11192020.csv
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sartan_30_final_11192020.csv

sartan_32_final_11192020.csv

sartan_33_final_11192020.csv

sartan_35_final_11192020.csv

ATTACHMENT C